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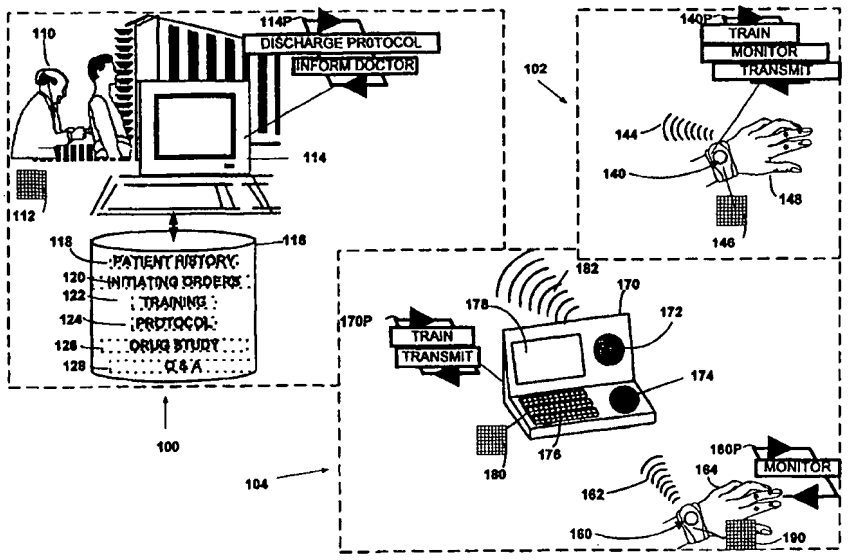
(54) Title: CYBER MEDICINE DISEASE MANAGEMENT

(57) Abstract

The subject health monitoring system is designed to supplement in an embodiment of the invention the health care efforts in caring for patients confined to their homes. The system may also be utilized within a facility such as a nursing home for monitoring patients within the home. The system integrates components distributed between a hospital and/or a central monitoring office to provide improved monitoring of these patients. The system provides for the translation of initiating orders into a computerized format. The system further provides for the programming of a patient monitoring unit at the remote site with the specific protocols consistent with the diagnoses of the doctor, as indicated on the initiating order. The system further provides for computerized training and prompting of the patient to assure their compliance with the initiating orders. Additionally, the system provides for intelligent communication between the remote site and the central office when appropriate. The system provides for the transmission of relevant data from the remote site to the central office when a critical event occurs. The system also provides for notification and graphical presentment to the doctor of trending of the patients biometric parameters. The trending parameters computed and presented to the doctor are disease specific, thus making for a more timely response. Finally, the system provides for the accumulation of a statistically normalized database correlating various medications as to their efficacy, duration, and side effects.



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CYBER MEDICINE DISEASE MANAGEMENT

BACKGROUND

Field of the Invention

This invention relates to a method and apparatus for monitoring a subject. More particularly this invention relates to monitoring a patient at a remote site from a central station.

Prior Art

Modern society with its improvement in living conditions and advanced health care has brought about a marked prolongation of life expectancy. This change has resulted in a dramatic and progressive increase in the geriatric population. A large percentage of the geriatric population needs continuous general, as well as medical, supervision and care. For example, supervision of daily activities such as dressing, personal hygiene, eating and safety as well as supervision of their health status is necessary. Furthermore, the relief of loneliness and anxiety is a major, yet unsolved, problem that has to be dealt with. These and other facets of the management of the ever increasing geriatric population have yet to be successfully addressed and solved.

The creation of retirement facilities and senior housing, as well as other geriatric facilities, provide only a partial solution to the problems facing the geriatric population. The geriatric population, a constantly increasing fraction of society, has

become increasingly dependent upon the delivery of home health and general care, which has its own set of challenges and drawbacks.

The notion of ambulatory (home environment) patient care is gaining increased popularity and importance. According to some recently published reports, the number of senior persons receiving home care services under Medicare has shown a 13% annual growth rate and has tripled in 10 years (1978-1988) from 769,000 to 2.59 million. This dramatic shift in patient care from the "sheltered" institutional milieu to the patient's home, work place, or recreational environment is due primarily to a radical change in concepts. That is, specialists in geriatric care recommend keeping the aging in their own natural environment for as long as possible. Moreover, the marked increase in the cost of institutional patient care, the important technological advances and the development of medical equipment, and the explosive development in the field of telecommunication are some of the additional factors that may help in creating proper home care for the aged.

Presently, geriatric home care is still in its first stages of development. However, according to some recently published market research reports, the market for home care services and products is booming. Annual spending on home care services is estimated to have increased from $8.8 billion in 1988 to $16 billion in 1995, while annual spending on home care products is estimated to have increased from $1.15 billion to $1.86 billion during the same period. Changes in healthcare also extend to the locale for the provision of care to non-geriatric populations. Home

care for these persons with acute or chronic illnesses has gained in popularity as institutions sited care has receded.

Except for limited supervised housing arrangements, non-medical home care is carried out either by the patient's family or by nonprofessional help. The monitoring equipment at home care facilities is usually minimal or nonexistent. The patient has to be transported to the doctor's office or other diagnostic facility to allow proper evaluation and treatment. Patient follow-up is done by means of home visits by nurses which are periodic in nature, time consuming, and generally very expensive. A visiting nurse can visit 5-6 homes per day. The visits are limited in time and can usually not be carried out on a daily basis to an individual patient. Moreover, a visiting nurse program provides no facilities for continuous monitoring of the patient and thus, no interventional care, except in fortuitous circumstances in times of emergency. The remainder of day after the visiting nurse has left is often a period of medical isolation and loneliness for the elderly patient.

The existing home care nursing organizations divert skilled nurses, a scarce commodity, from the hospital environment and use them in a highly inefficient manner due to travel time to widely dispersed patients and the lack of sophisticated diagnostic capabilities in the patients' home. Clearly, the practice of visiting nurses is constrained.

These above considerations, which apply to the general population, as well as the spiraling cost of hospital care have led to a dramatic increase in the use of outpatient care as a treatment modality.

One of the areas in which ambulatory patient monitoring is most widely used is out-of-the-hospital surveillance of the cardiac patient. Patients with cardiovascular problems (diseases of the heart and blood vessels) constitute the largest and most important diagnostic and therapeutic challenge facing the authorities responsible for the deployment of health care to the adult and specifically aging population in the U.S. About 15% of the adult population of the industrialized world suffers from hypertension, a major risk factor for atherosclerosis, heart disease, and stroke. Other commonly accepted risk factors such as: elevated blood lipid levels, obesity, diabetes, smoking, mental stress and others are abundant.

Every year more than 1.5 million people in the U.S. suffer a heart attack. This together with a stroke constitutes the number one cause of death in our adult population. More importantly, the majority of cardiac related deaths occur outside of the sophisticated and sheltered hospital environment. Therefore, the need for means for ambulatory monitoring of these patients is obvious.

To date the electrocardiogram (ECG) and blood pressure are two main parameters most commonly monitored in the out-of-the-hospital environment. Holter monitoring (continuous 24 hour tape recording of the electrocardiogram) and continuous recording of blood pressure are useful modalities for the evaluation of changes in the cardiovascular system. These, however, are short term monitoring systems that provide only off line information that becomes available at best hours after their recording. Moreover, the hook up should be done by a nurse or technician.

Lately, transtelephonic ECG surveillance has been gaining in importance. This system uses small ECG transmitters which allow the transmission of the patients ECG over any telephone line to a diagnostic center. This on-line information system is operative 24 hours a day, 365 days a year. The patient is in direct contact with a highly trained team that can intervene at any time and make real time decisions. The drawback of this system is its communication system, which does not lend itself to prolonged monitoring sessions and does not allow for visual observation of the subject.

A home medical surveillance system is described in U.S. Pat. No. 4,838,275, issued to Lee. This system involves the generation and transmission of health-parameter signals from a patient's home to a central station. However, the described system envisions only two way voice communication between the patient and the observer at the central station. This system does not provide for interactive visual communications between the patient and health care provider, and thus lacks a principal feature and advantage of the present invention.

U.S. Pat. No. 4,524,243, issued to Shapiro discloses a personal alarm system in which a warning signal is sent to a central monitoring station if the patient's activity level becomes inactive, such as in the case of a medical emergency. This technology is limited in its diagnostic and therapeutic value, and does not, in and of itself, provide for interactive voice or visual communication between the patient and the physician.

Other patents disclose techniques for the transmission of still medical images over a communications line to a remote site. For example, U.S. Pat. No. 4,860,112, issued to Nichols et al., discloses methods and apparatus for scanning medical images such as x-ray images and transmitting the scanned image to a remote location. U.S. Pat. No. 5,005,126, issued to Haskin, discloses a system for picking off an internal analog video signal from imaging diagnostic equipment such as a CAT scanner and transmitting the image to a remotely located physician's station. U.S. Pat. No. 4,945,410, issued to Walling, discloses a satellite communications system for transmission of still medical images from a remote satellite transmission station to a central headquarters. These patents have their own inherent limitations and lack the interactive audio and visual capabilities provided by the present invention.

There exists, at present, home health care and monitoring products that perform various functions. The simplest include, amongst others, instruments such as self-operated blood pressure devices (sphygmomanometers), blood glucose measuring instruments, automated medication dispensers and others. While these products are designed to be useable by a patient without any assistance, they have no inherent capability of remote monitoring. Moreover, they are often difficult to use by elderly or infirm patients.

The other end of the spectrum includes the development of computer controlled robots that provide an integrated, highly sophisticated, home based monitoring unit. An example of such a device is the HANC (Home Automated

Nursing Center) system described in U.S. Pat. No. 5,084,828, issued to Kaufman et al. This patent includes a robot capable of monitoring the patient's vital signs, reminding the patient of his or her medications, dispensing them in due time, and contacting a control center for routine follow-up as well as in emergency situations. This device is generally an unsatisfactory solution to the problem of at-home patient monitoring because it is extremely expensive, cumbersome, and lacks interactive communication capabilities between the patient and their physician.

The complex robotic units and home computer are impressive in their capacity, they but lack the human contact which is so important in effective geriatric care. The patient's interaction with a machine, as sophisticated as it may be, will always be inferior to the direct human contact. Moreover, these systems are very expensive and will in the foreseeable future be available to only a very small number of patients who can afford them. Moreover, the older population does not adjust easily to computers

and robots, and mistakes in their use are frequent. Maintenance and problems and the difficulty in programs in the computerized system make the upkeep more complex. Thus, the currently available techniques for providing home patient monitoring, particularly of the elderly, leave much to be desired.

Additional facts support development of an improved home health care system especially for a geriatric population. For example, falls are a major health problem among the elderly, causing injury, disability and death. One third (some studies suggest half) of those over the age of 65 suffer at least one fall each year.

The rate of falling increases to 40% among those who exceed the age of 80. According to the National Safety Council, falls accounted for one-third of the death total for the elderly. Those who survive falls may have restricted activity, soft-tissue injuries, or fractures. It is estimated that up to 5% of falls by elderly persons result in fractures. A similar percent result in soft-tissue injury requiring hospitalization or immobilization for an extended period. It is estimated that hip fractures resulting from falls cost approximately $2 billion in the United States during 1980. Falls are mentioned as a contributing factor to admissions to nursing homes.

The factors leading to falls can be divided into two main groups: environmental factors and medical factors. In spite of the difficulty in the surveillance of patient condition before a fall, almost all researchers share the conclusion that environmental hazards are decreasingly important in causing falls as age increases. A clear correlation between clinical or medical problems and the incident of falls by the elderly has been established. Many of these medical problems of the elderly or infirm can be detected by simple clinical observation. For example gait, and balance abnormality may indicate difficulty with neurologic and musculoskeletal functions that may contribute to physical instability. Changes in gait can be identified by the following: slow speed, short step length, narrow stride width, wide range of stepping frequency, a large variability of step length, and increasing variability with increasing frequency.

Thus, there are relatively straight forward techniques which enable diagnosis of a predisposition or likelihood of falls among elderly. However, there is no

inexpensive procedure for undertaking such diagnosis or investigating such predisposition in a large patient population, wherein the kinematic condition of the patient can be investigated or where the appearance, and reflex activity of the patient can be investigated with ease.

Accordingly, there is a need for improved methods and devices for (remote monitoring patients.

SUMMARY OF INVENTION

The invention has the benefit of allowing multiple remote sites to continuously monitor patient data. Each of the remote cites is equipped with a user configurable decision making process to determine when to transmit patient data. When the programmable processor that is detecting patient data determines that one or more of the vital signs being monitored exceeds a threshold determined by a position then the data for that vital biometric parameter as well as the data concurrently obtained from the monitoring of other biometric parameters is retrieved from the respective storage buffers and transferred to the monitoring site. This selective broadcasting only under unstable or alarming conditions from plurality of patients to receiving cite assures that only those patients requiring attention are broadcasting data to the receiving cite. When an alarm condition occurs the

physician has the opportunity to review relevant history for better determining the severity and immediacy of the condition.

In an embodiment of the invention a computer implemented method for managing the care of a patient on the basis of a discharge order containing a diagnosis of at least one disease of the patient is disclosed. The method for managing comprising the acts of:

determining a protocol for monitoring the patient, the protocol including at least one biometric parameter to be monitored and at least one response associated therewith;

monitoring the at least one biometric parameter; and

executing the at least one response associated with the biometric parameter when the biometric parameter is beyond a selected threshold.

BRIEF DESCRIPTION OF THE DRAWING

In the detailed description of presently preferred embodiments of the present invention which follows, reference will be made to the drawings comprised of the following figures, wherein like reference numerals refer to like elements in the various views and wherein:

FIG. 1 is an overall functional block diagram of a first embodiment of the patient monitoring system of the present invention;

FIG. 2 is a hardware block diagram of the portable patient monitor shown in FIG. 1 for monitoring and training a patient at a remote site and for transmitting data directly from the remote site to a central office when appropriate.

FIG. 3 is a hardware block diagram of the portable patient monitor shown in FIG. 1 for monitoring a patient at a remote site and for transmitting patient biometric parameters to a patient monitoring computer at the remote site.

FIG. 4 is a hardware block diagram of the patient monitoring computer shown in FIG. 1 at the remote site.

FIG. 5 shows the software modules associated with the central office and remote site.

FIG. 6 shows an embodiment of the data structure associated with discharge orders for a patient.

FIG. 7A-C show the data structures associated with the disease specific protocol records of the current invention.

FIG. 8 is a graph showing representative signals obtained from monitoring biometric parameters.

FIG. 9 is a process flow diagram of the processes associated with the monitoring a patient at the central office shown in FIG. 1.

FIGS. 10A-B are process flow diagrams of an embodiment of the invention which show the processes associated with monitoring a patient at respectively the remote site and the central office.

FIGS. 11-17 are process flow diagrams of the processes at the remote site for monitoring specific disease states according to an embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The patient health monitoring system is designed to supplement the health care efforts in caring for patients confined to their homes. The system may also be utilized within a facility such as a nursing home for monitoring patients within the home. The system integrates components distributed between a hospital and/or a central monitoring office to provide improved monitoring of these patients. The system provides for the translation of physician orders: including traditional discharge, or patient transfer orders, into a computerized format. In a healthcare setting an initiating order may be generated by a physician for a patient in a health care facility such as a hospital or nursing home, or for a patient leaving such facilities, or for a patient in an ambulatory setting. As will be obvious to those skilled in the art other settings exist for initiating orders, including non-medical settings such as biologic monitoring of normal subjects both human and animal. The system further provides for the programming of a patient monitoring unit at the remote site with the specific protocols consistent with the diagnoses of the doctor, as indicated on the initiating order. The system further provides for computerized training and prompting of the patient to assure their compliance with the initiating orders. Additionally, the system provides for intelligent communication between the remote site and the central office when appropriate. This latter capability reduces the time required at the central office to monitor patients, yet assures that critical events occurring during patient monitoring will not be overlooked. The system provides for the transmission of relevant data from the remote site to the central office when a

critical event occurs. The system also provides for notification and graphical presentment to the doctor of trending of the patients biometric parameters. The trending parameters computed and presented to the doctor are disease specific, thus making for a more timely response. Finally, the system provides for the accumulation of a statistically normalized database correlating various medications as to their efficacy, duration, and side effects.

FIG. 1 is an overall system diagram of an embodiment of the patient health monitoring system of the current invention. Shown in FIG. 1 are Hospital/Central Monitoring Office 100, a first embodiment of the patient monitor is shown at site 102, and a second embodiment of the patient monitor is shown at site 104. The Hospital/Central Monitoring Office includes a computer 114 with access to a storage device 116. A "one-piece" version of the remote monitoring system 102 includes portable patient monitor 140 also known as patient monitoring device, which may include a display, microphone, camera, speaker and biometric sensors, and is constructed to be attached to patient 148. This version features a portable patient monitor that includes monitoring, training and transmitting functions in one device, which is attached to the patient. A "two-piece" version of the remote monitoring system may include a portable patient monitor 160 also known as patient monitoring device, with a display, speaker and sensors and is constructed to be attached to patient 164. This version of the remote monitoring system also includes patient monitoring computer 170, which may include camera 172, microphone/speaker 174, keyboard 176, and display 178. The two-piece version of

the remote monitoring system facilitates a reduction in the size of the portable patient monitoring unit by packaging several functions in the patient monitoring computer.

Computer 114 may access a plurality of databases in storage device 116. Six databases are shown specifically: patient history database 118, initiating order database 120, training database 122, protocol database 124, drug study database 126, and question & answer ("Q&A") database 128. The patient history database contains records pertaining to the medical history of various patients treated at the Hospital/Central Monitoring Office 100. Such records may be created by health care workers during their care of the patient. The initiating orders database contains records with information corresponding to the initiating orders 112. The discharge order may be used by the patient monitoring system in generating a protocol record that may be used in the monitoring of the patient according to the invention. The initiating order also serves as a starting point for further treatment plans by health care workers. The training database contains records such as audio clips, short visual displays or films, and text-based messages. These records contain information that instructs patients how to use the various sensors which are part of or connected to the portable patient monitor at the remote site. The drug study database contains records that relate to use of data generated through operation of the patient health monitoring system for developing new or improved drugs. The Q&A database includes records with predetermined questions appropriate for a specific disease state or for response to a particular event detected by the monitoring system.

These questions may be used, for example, to interrogate the patient about the patient's condition or about the relevance of the information received through sensors in the portable patient monitors, etc. The records may be audio files which can be played to the patient by the remote monitoring system in order for that system to record the patients answers and transmit them to the doctor.

In the one-piece design for monitoring equipment shown at site 102 (See FIG. 1) the portable patient monitor 140 contains a file 146, which contains the code associated with performing the training, monitoring, and transmitting functions corresponding to the particular disease state with which the doctor characterized the patient in the initiating order. In contrast, the two-piece design for monitoring equipment at site 104 (See FIG. 1) the portable patient monitor 160 contains within it a file 190, which contains code associated with monitoring the patient. The remaining code is contained in the patient monitoring computer 170 in file 180, which contains code and associated Q&A and training files for training a patient and for transmitting patient data to the central office when appropriate.

In operation, physician or other permitted health care professional 110 enters initiating orders 112 into computer 114, which stores them in initiating order database 120. The initiating orders include information regarding personal information, insurance, diagnoses, and prescribed medications. Initiating orders are described in more detail below. From the initiating order database, patient history database 118, training database 122, protocol database 124, and Q&A database 128, the processes 114P generate a management record. The management record is then

transmitted to a remote monitoring system. Typical management records include information such as types and frequency of medication to be administered, types of sensors to be used, training files and Q&A files that might be appropriately associated with carrying out the protocol.

The management records are downloaded to remote monitoring systems, such as the one-piece and two-piece systems. In the case of patient monitoring system 140, processes 140P are implemented by portable monitoring device 140 for monitoring the patient, for training the patient in the use of monitoring devices, or sensors for selecting the time of day to monitor, and for deciding when to transmit data from the remote site to the central office. All of these processes may be implemented on a disease specific basis, each with its own different monitoring protocol. Results from the monitoring carried out by the portable patient monitor are transmitted 144 back to the Hospital/Central Monitoring Office 100 by processes 140P. The portable patient monitor may buffer the results until it is appropriate to transmit them. Likewise, at site 104, portable patient monitor 160 implements processes 160P to monitor the patient's condition, and to transmit the monitoring results to the patient monitoring computer (PMC) 170, as suggested by element 162. File 190 contains code to direct these activities. The patient monitoring computer implements processes 170P to display training information and to transmit 182 back to the Hospital/Central Monitoring Office 100 the results of the monitoring. The patient monitoring computer may buffer the results until it is appropriate to transmit

them. File 180 contains the information and code necessary for the training and transmitting functions carried out by the patient monitoring computer.

FIG. 2 is a detailed hardware block diagram of the one-piece version of the portable patient monitor 140, shown in FIG. 1 attached to patient 148. The one-piece portable patient monitor serves to monitor various sensors, to transmit data, and to train the patient in various functions. The one-piece patient monitor includes microprocessor 202, buffer memory 210, limit memory 212, screen or audio driver 206, key interface 208, cellular transceiver 204, storage device 224, display or audio output device 240, sensors 242 and 244 and confirmation switch 246 also called enabling switch. Buffer 210 comprises individual buffers 216 and 218 for respectively the last hour of data received from sensors 242 and 244. Limit memory 212 comprises limit memory 220 and 222 to store, respectively, established values for triggering events.

In operation this system performs as follows. Storage device 224 contains within it a management record file 146 received from a central monitoring station (not shown). The management record includes instructions concerning which sensors to read, when to take readings of those sensors, information as to what levels of sensor readings or times, etc., might serve as triggering events, and also training and Q&A files for display by the display or audio output device 240. The file containing the management record may be updated as desired by transmitting information from the central monitoring station, which is received by cellular transceiver 204. Signal unit 214 is in continuous receipt of signal corresponding to

the biometric parameters being monitored by sensors 242 and 244. These sensors may be selected according to the patient's situation, but often will include such baseline parameters as blood pressure, pulse, temperature, and respiratory rate. This data is continuously stored in buffers 216 and 218. The data in these buffers is continuously monitored according to reprogramable signal limits stored in memory units 220 and 222. When microprocessor 202 detects that any single limit or combination of limits in any arrangement according to the management record is triggered, then the data in all buffers is passed to cellular transceiver 204 for wireless transmission to the central monitoring office.

When this packet of data is received by the central monitoring office, additional data may be requested from the remote site. The user may be requested to confirm the severity of the bodily dysfunction. Patient confirmation may be sent by the patient, in this case by enabling switch 246 to key input 208, and wirelessly transmitted via transceiver 204 to the central monitoring office. This data along with the biometric parameter data is included in a packet available for the health care worker who is made aware of this packet. At appropriate times, such as upon the occurrence of a triggering event, training information may be displayed for the patient using display 240. Such training information is contained in the training record which forms part of the management record. The training information may show the patient how to use the device. The training information may show the patient how to hook up additional sensors to the portable patient monitoring device,

or how to properly position the existing sensors 242-244 to attain a proper biometric parameter reading.

FIG. 3 is a hardware block diagram of the portable patient monitor portion of the two-piece version of remote patient monitoring system shown in FIG. 1. The two-piece monitor serves to monitor various sensors and transmit them to a patient monitoring computer (not shown). The portable patient monitor 160 includes sensors 320 and 318, handshake confirmation switch 302, A/D converter 316, timer 308, display 306, encoder 310, decoder 312, and transceiver unit 304. Decoder 312 contains a modified version of the management record in file 190 that may contain only the information needed to monitor patient data. The patient data is received from sensors 320 and 318 and is converted to digital form in A/D unit 316. The separate signals are then passed to encoder 310 where they are tagged within identifier indicating which biometric parameter, i.e., to which sensor the digital signal corresponds. These signals are sent via receiver 304 to the patient monitoring computer, for further processing, upon the occurrence of a triggering event, as is defined in the modified management record.

FIG. 4 is a hardware block diagram of the patient monitoring computer portion of the two-piece version of the remote patient monitoring system shown in FIG. 1. The patient monitoring computer serves to transmit and receive data to the central monitoring office (note shown) and to provide training and Q&A information to the patient, when appropriate. The two-piece patient monitor includes microprocessor 402, buffer memory 410, limit memory 412, audio driver 406, key

interface 408, cellular transceiver 404, storage device 424, video/audio output 440, video input 442, signal unit 430, short range transmitter 432, and short range receiver 434. Buffer 416 comprises individual buffers 416 and 418 for data received from sensors contained in the portable patient monitor, shown in FIG 3. Limit memory 412 comprises limit memories 420-422 to store established values for triggering events.

In operation this system performs as follows. Storage device 424 contains within it a management record file 180 received from the central monitoring station shown in FIG. 1. The management record includes program codes for: sensors to read, when to take readings of those sensors, information as to what levels of sensor readings or times, etc., might serve as triggering events, and also training and Q&A files for display by audio output device 440, or video output 440 under appropriate circumstances. The management record file may be updated as desired by transmitting information from the central monitoring station, which is received by cellular transceiver 404. Portions of the management record relating to monitoring are sent to the portable patient monitor 160 via short range transmitter 432. These instructions serve to guide the operation of the portable patient monitor, as discussed above in FIG. 3. In return, the portable patient monitor sends signals that are received by short range receiver 434 and are processed by signal unit 430. These signals are from devices in the portable patient monitor, and may be selected according to the patient's situation, but often will include such baseline parameters as blood pressure, pulse, temperature, and respiratory rate. This data is continuously

stored in buffers 416-418. The data in these buffers is continuously monitored according to reprogramable signal limits stored in limit memories 420-422. When microprocessor 402 detects that any single limit or combination of limits in any arrangement according to the management record is triggered, then the data in all buffers is passed to cellular transceiver 404 for wireless transmission to the central monitoring office. Additionally, video input 442 may be used to receive video data as needed to evaluate the patient's condition. At appropriate times, such as upon the occurrence of a triggering event, training information may be displayed for the patient via video output 440. Such training information is contained in the training record which forms part of the management record.

FIG. 5 shows a software block diagram that illustrates software operations in one embodiment of the patient health monitoring system according to the invention. Shown are the software modules associated with hospital/central monitoring office 100 and with portable patient monitor (See FIG. 1). The software modules associated with hospital/central monitoring office 100 includes translation module 500, notification module 502, and graphical user interface module 504. The software modules associated with portable patient monitor includes control module 554, event module 550, training module 552, timer module 556, recording module 558, and sensing module 560.

Translation module 500 receives initiating order 112 as an input. The translation module additionally interfaces with the databases contained in storage device 116, which has been discussed above in more detail. The translation module

also outputs and downloads a management record 582 based on the information contained in the various databases and initiating orders. The translation module may receive an uploaded event record as an input from portable patient monitor . The translation module then outputs information from the uploaded event record to notification module 502. The notification module then may output this information to graphical user interface module 504, which displays the information on display 506 for a health care worker to see.

Control module 554 receives a downloaded management record 582 as an input. The control module then outputs the triggering event portion of the record to the event module 550, and the training portion of the record to training module 552. The training module outputs the training portion of the record upon instructions to do so from the control module. The control module additionally interfaces with timer module 556 to track time. The control module interfaces with the sensing module to switch it to the appropriate ones of the sensors 590-594. The control module also receives input from sensing module 560 and from recording module 558, regarding input from the selected ones of sensors 590-594. Sensing module 560 receives input from sensors 1-3, (elements 590, 592, and 594, respectively) and then outputs the information to both the control module and the recording module. The recording module stores the information from the sensing module and transmits it to the control module at an appropriate time.

In operation, translation module 500 receives initiating order 112, stores it in the initiating order database 120, and then assembles a management record based on

the initiating order, and the patient history, training, protocol, drug study (if applicable), and Q&A databases. This management record is downloaded as program code and data files to portable patient monitoring device . Additionally, upon receipt of an uploaded event record 580, the translation module functions to activate notification module 502, which notifies a health care worker. The notification module can then drive graphical user interface 504, which uses display 506 to display the contents of the uploaded event record for the health care worker at hospital/central monitoring station 100.

In portable patient monitor , the control module functions to coordinate the flow of information to and from the hospital/central monitoring station. Upon receiving the downloaded management record, the control module divides up the record and distributes the relevant information to the various functional modules, such as the event, training, sensing, and recording modules. The control module also serves to coordinate the flow of information upon the occurrence of a triggering event. Such an event, detected by the event module based upon information delivered to it by the sensing module or the timing module, results in the control module assembling the event record to be uploaded, if necessary, from information provided to it by the recording and sensing module. A triggering event may also result in the activation of the training module by the control module, with the attendant displaying of training information to the patient. Such information may be used to train the patient in the proper attachment of external sensors to the portable patient monitors 140, 160 or to the patient monitoring computer 170 (See FIG. 1).

FIG. 6 shows a plurality of records, labeled 600, 602, and 604, that correspond to initiating orders. Physician orders, e.g. initiating orders may be generated by a patient's physician or assistant and may be generated at the time a patient is released from a hospital or other care setting. Each initiating record may contain patient information in fields 610, diagnosis in field 612, and medication information in fields 614. As will be obvious to those skilled in the art the diagnosis field may include more than one diagnosis.

As shown in initiating record 600 patient information field 610A includes name (John Smith), age (66), sex (male), residence (11 Oak Street), Insurance (Everlast), and physician name (Dr. Fine). Diagnosis field 612A contains the diagnosis (diabetes) for the patient who has been described in patient information field 610A. Medication fields 614A contains the prescription from the patient's physician to describe a medication and its dosing regimen for the patient. In the medication fields, inputs are accepted for type of medication (insulin), route of administration (subcutaneous), the name of the medication (NPH), the frequency of administration (2x/daily), and the dose per administration (20 Units). Additional medications may be included in the initiating orders in similar formats.

Initiating records 602-604 contain similar information to initiating record 600, but for Lucile Jones, and Donna Hengst, respectively. In record 602, the patient information for Lucille Jones is contained in patient information field 610B. The diagnosis for Lucile Jones (congestive heart failure) is contained in diagnosis field 612B. The appropriate medication for the patient (ACE inhibitor) is contained in

medication field 614B. Similarly in initiating record 604, the patient information for patient Donna Hengst is contained in patient information field 610C, the diagnosis (hypertension) is contained in diagnosis field 612C, and the medication (calcium channel blocker) is contained in field 614C.

FIGS. 7A-C show examples of three initiating protocol records. These example records illustrate the preferred monitoring protocols for diabetes, congestive heart failure, and high blood pressure, respectively. These records are part of the protocol database as shown in element 124 in FIG. 1. Each protocol record generally contains detailed instructions to be transmitted to the remote monitoring equipment, along with corresponding Q&A and training files.

In FIG. 7A, diabetes protocol record 700 includes primary biometric field 710A, frequency/time field 712A, sensor field 714A, additional sensor field 716A, baseline biometric field 718A, display type field 720A, Q&A file field 730A, training file field 732A. Also included is random field 734A, which may be used as part of a drug study.

Primary biometric field 710A contains information about the primary biometric to be monitored, in this case, glucose. The frequency and time field, 712A, contains information about both the frequency and the time period in the day in which to monitor for the primary biometric. In this case, glucose is to be monitored twice daily, once at 9:00 a.m. and once at 4:00 p.m. Sensor A field 714A describes a first sensor to be used, and also includes information about what received values of sensor A may be considered to be triggering events. Field 716A describes

sensor B, which is in this case a finger prick blood glucose test. Also contained in field 716A, in a similar fashion to field 714A, are various values of results from the sensor which will trigger different responses from the portable patient monitoring system. Baseline biometric field 718A contains information about whether the patient is to be monitored for baseline biometric parameters such as: blood pressure, pulse, temperature and respiration rate. Display fields 720A contain information about how to display information accumulated during the monitoring operation of the patient health system so as to allow for focused rapid physician response to an event detected by the remote patient monitoring system. Q&A field 730A contains a file that has various questions that could be accessed in the course of obtaining subjective information from the patient during the monitoring process. Training field 732A contains training files that can be used to train the patient in the use of monitoring equipment, or the attachment of existing or additional biometric sensors. Random field 734A contains information about when to randomly include an additional monitoring of the patients biometric parameters. By requiring for example, each patient in the remote population to perform an additional test, e.g. finger prick and blood sample, information on the efficacy and durability of a specific drug can be obtained. This information is obtained through the aggregation of information from each member of the patient population under the control of the central monitoring station.

Elements 714A-716A contain information instructing the remote monitoring equipment how to respond to particular ranges of the biometric parameters being

sensed. For example, if sensor A is employed for testing the patient's urine and the result is 1+, the regime is maintained. However, if the response is 2+, then the patient is instructed to employ sensor B. Fields 716A correlate glucose levels obtained by blood samples obtained by finger prick with appropriate responses. At a level of glucose less than 150 mg/dl the existing regimen is maintained. At a level between 150 and 250 mg/dl an additional 5 units of insulin should be administered. At a level between 250 and 350 mg/dl an additional 10 units of insulin should be administered. At levels above 350 mg/dl the patient should be asked the questions in the Q&A file and the answers to those questions should be recorded. The information including biometric parameters, patient responses to questions, etc., should then be sent to the central office. When the information is received by the central office the event may be brought to the attention of a doctor.

In FIG. 7B, congestive heart failure protocol 702 includes primary biometric field 710B, frequency field 712B, sensor field 714B, additional sensor field 716B, baseline biometric field 718B, display type field 720B, question and answer file field 730B, training file field 732B. Also included is random field 734B, which may be used to normalize drug studies by inserting an additional monitoring time for each drug so that collectively from various other sites at which the drug is being used as well as this site, time sampled information on the performance of each drug can be obtained.

Primary biometric field 710B contains information about the primary biometric to be monitored, in this case, congestive heart failure. The frequency and

time field, 712B, contains information about both the frequency and the time period in the day in which to monitor for the primary biometric. In this case, fluid retention is to be monitored once daily, at 9:00 a.m. Sensor field 714B describes a sensor A and a sensor B to be used, and also includes information about what received values of sensor A-B may be considered to be triggering events. Field 716B describes sensor C, which is in this case a blood oxygen test. Also contained in fields 714B-716B are various values of results from the sensors that will trigger different responses from the portable patient monitoring system. Baseline biometric field 718B contains information about whether the particular biometric is actually enabled or not enabled, instructing the remote monitoring equipment as to whether or not to monitor this particular biometric. Display fields 720B contain information about how to display information accumulated during the monitoring operation of the patient health system. Question and answer field 730B contains a file that has various questions that could be accessed in the course of obtaining subjective information from the patient during the monitoring process. Training field 732B contains training files that can be used to train the patient in the use of monitoring equipment. Random field 734B contains information about when to randomly include an additional test, for drug study purposes.

Elements 714B and 716B contain information instructing the remote monitoring equipment how to respond based on the particular condition. For example, sensor A is employed for testing the patient's weight and sensor B is employed for measuring the patient's edema. In the setting of congestive heart

failure fluid congestion in the lungs may be indicated by a fall in SAO_2 and fluid retention in the body will be indicated by a rise in body weight. If the result is a weight gain of two or more pounds and there is an increase in edema reading of more than 15%, then the patient is instructed to take 20 mg. of furosemide. If the patient gains more than five pounds, then regardless of the edema reading, the patient is instructed to take 20 mg. of furosemide. However, if the result is a weight gain of five or more pounds and there is an increase in edema reading of more than 20%, then the patient is instructed to employ sensor C. In sensor C, element 716B, the results of a blood oxygen test are used to determine whether it is appropriate to maintain the regimen (SaO_2 >92%) ; recheck the blood oxygen (SaO_2 is 90-92%) in twelve hours; or play a question and answer file contained in field 730B, and notify the central monitoring station (SaO_2<90%) with an appropriate event record, including the Q&A results.

In FIG. 7C, high blood pressure protocol 704 includes primary biometric field 710C, frequency field 712C, sensor field 714C, baseline biometric field 718C, display type field 720C, question and answer file field 730C, training file field 732C. Also included is random field 734C, which may be used as part of a drug study.

Primary biometric field 710C contains information about the primary biometric to be monitored, in this case, blood pressure. The frequency and time field 712C, contains information about both the frequency and the time period in the day in which to monitor the primary biometric. In this case, blood pressure is to be

monitored four times daily, once at 8:00 a.m., 12:00 noon, 6:00 p.m, and 10 p.m. Sensor A field 714C describes a sensor to be used, and also includes information about what received values of sensor A may be considered to be triggering events. Also contained in field 714C are various values of results from the sensor which will trigger different responses from the portable patient monitoring system. Baseline biometric field 718C contains information about whether the particular biometric is actually enabled or not enabled, instructing the remote monitoring equipment as to whether or not to monitor this particular biometric. Display fields 720C contain information about how to display information accumulated during the monitoring operation of the patient health system. Question and answer field 730C contains a file that has various questions that could be accessed in the course of obtaining subjective information from the patient during the monitoring process. Training field 732C contains training files that can be used to train the patient in the use of monitoring equipment. Random field 734C contains information about when to randomly include an additional blood pressure test, for drug study purposes.

Element 714C contains information instructing the remote monitoring equipment how to respond based on the particular condition. For example, if sensor A is employed for testing the patient's blood pressure and the result is a systolic blood pressure less than 90 mm Hg then the patient is instructed to recheck her blood pressure in one hour. However, if the result is either systolic greater than 200 or less than 80, then the monitoring system plays a question and answer file contained in field 730C, and notifies the central monitoring station with an

appropriate event record, including the Q&A results. As will be obvious to those skilled in the art additional biometric parameters may be monitored including diastolic pressure. Also other responses may be substituted without departing from the teachings of this invention.

FIG. 8 is a graph showing two hypothetical signals 850 and 856 which might be generated by sensors present in the portable patient monitoring devices 140,160 (See FIG. 1). These signals in digital form would be stored in first in first out fashion (FIFO) as above discussed in separate buffers in buffer memories 210 or 410 (See FIGS. 2,4). An upper and lower limit also called thresholds 852 and 854 is shown in connection with signal 850 and an upper and lower limit 858 and 860 also called thresholds respectively is shown in connection with signal 856. These limits correspond to the above discussed limits which would be stored in limit memories 212 and 412 (See FIGS. 2,4). The graphical snapshot is shown commencing at time T1. At time T2 signal 850 has passed beyond upper threshold 852. If the physician has programmed limit memory in such a way as to require that the passage of this one biometric parameter beyond its upper limit is sufficient to trigger an alarm condition then in this instance, the data contained in both the buffer for signal 850 and the buffer for signal 856 will be uploaded and transferred via wirelessly to remote receiver 46. Thus, at the time the alarm condition is triggered, not only the immediate physiological data for the patient is transferred but also that data which occurred during the buildup to this alarm condition, i.e. the historical data. Data is continuously transmitted during the interval between time 2 and time 3. T3

corresponds to the point at which the biometric parameter e.g. the signal 850 has returned to an amplitude below upper threshold 852. Of course it is possible that the biometric parameter indicated by signal 850 would not return below the upper limit 852 in which case data would be locked in a continuous transmit condition until such time as the patient received attention or the biometric parameter being monitored returned below the upper threshold, indicated by T3. For an appropriate amount of time in this case indicated as the interval between T3 and T4 after a given biometric parameter triggering an alarm condition returns below the threshold condition which caused the alarm condition, data will continue to be transmitted in real time to the central office. At time T4 data may cease to be transmitted, having normalized for a sufficient interval. Alternately, data may continue to be transmitted until a physician indicates otherwise. As will be obvious to those skilled in the art, the reprogramable feature of the current invention and the programming feature itself allows any combination of upper and lower limits at any number of biometric parameters in any combination or grouping to be the condition upon which an alarm condition should be generated. For example, a rise in heart rate to a certain level unaccompanied by a corresponding fall n some other biometric parameter such as blood pressure may not, according to the physician, be a cause for triggering an alarm condition. This more complex thresholding condition is stored in limit memory. As will also be obvious to one skilled in the art, an alarm condition need not merely correspond to the amplitude of a biometric parameter but might

correspond to the frequency or increase in frequency of the biometric parameters, e.g., heart rate.

One who is skilled in the art will recognize that the alarm limits 852, 854, 858, and 860 may correlate to the integral of the biometric signal or to its derivative or to the ratio of two signals or to another mathematical operator.

Fig. 9 is a process flow diagram showing an embodiment of the processes 114P implemented at the central office 100 (see FIG. 1). Processing begins as decision process 902 in which a determination is made as to whether a new initiating order needs to be processed. The initiating order 112 (see Fig. 1) may be entered manually or electronically into the computer. When a new initiating order needs to be processed control is passed to process 904. In process 904 the disease listed in the diagnosis field 612 (see FIG. 6) is determined. Control is then passed to process 906. In process 906 the protocol record corresponding to the disease listed in the diagnosis field 612 is retrieved from the protocol database 124 (see FIG. 1). The protocol database contains as described and discussed above in connection with Figs. 7A-C contains protocol records for monitoring specific diseases. Control is then passed to process 908. In process 908 a comparison is made between the initiating record and the selected protocol record. Control is then passed to decision process 910. In decision process 910 a determination is made as to whether the physician or initiating order conflicts in any way with the selected protocol record. If for example the physician's medication or dosage amounts differ from those listed in the protocol record then control is passed to process 912. In process 912 the

conflict is brought to the attention of a physician so that they may resolve it before programming the remote monitoring system.

In the event there is no conflict between the physician initiating and the protocol record, or in the event that a physician has modified an existing protocol record to harmonize it with his/her initiating orders, then control is passed to process 914. In process 914 any files such as Q&A and/or training files associated with the protocol record are retrieved from respectively databases 122 and 128 (see FIG. 1). Control is then passed to process 916. In process 916 statistical information gathering processes are implemented for retrieving from this patient additional information useful for the aggregate characterization of the drug being utilized to treat this patient. This may take the form of an additional time of day at which to monitor the patient. This time may correspond to 1/2 hour after prescription dosage. If another patient treated with the same drug is monitored at 1 hour after prescription dosage, and so forth, a complete time weighted study of the drug efficacy and duration can be created from the aggregation of a plurality of patients. This time will be placed in field 734 (see FIG.7A-C). Control is then passed to process 918. In process 918 the management record including the Q&A and training records and the code associated with implementing the protocol record retrieved in process 906 are downloaded to the remote site. Control is then passed to decision process 920.

In decision process 920 a determination is made as to whether an event record has been received from a remote site. In the event that determination is in the negative, control is returned to decision process 902 for the processing of the next

initiating record. Alternately, if a decision is made that an event record has been received then control is passed to process 922. In process 922 a determination is made on the basis of the initiating record and specifically field 720 thereof as to what format of display and what combination of biometric parameters and/or question and answer sequences allows for the most targeted response on the part of the physician from the voluminous available patient data. This data is formatted according to the format indicated in field 720 (see Figs. 7A-C). The correct presentment of data can be crucial in a timely reaction to a possibly critical event which the patient has experienced and which the remote monitoring equipment has transmitted to the central office.

Control is then passed to process 924. In process 924 the data is gathered in the appropriate format for display to the physician. Control is then passed to process 926. In process 926 the patient history record for the patient with respect to which an event has been recorded is fetched from the patient history database 118 (see FIG.1). Control is then passed to process 928. In process 928 the doctor is notified that an event has been recorded that needs his/her attention. Control is then passed to process 930. In process 930 the targeted information discussed above in connection with processes 922-924 is displayed to the doctor to allow them to make a timely decision for managing the patient. Control then returns to decision process 902 for the detection of the input of the next initiating record.

FIG. 10A is a process flow diagram showing the steps connected with the operation of a first embodiment of the portable patient monitoring device shown in

FIG. 1. The process commences at 1000 where data is being obtained from the sensors processed and put into FIFO buffers corresponding to the respective sensors. The data in these buffers is continuously compared with the limits and limit conditions stored in limit memory in process 1002. Control is then passed a decision step 1004 in which a determination is made on the basis of the comparison as to whether an alarm condition corresponding to a limit, or a set of limits programmed by the physician has been exceeded. In the event this determination is in the affirmative then control is passed to decision process 1006. In process 1006, the transceiver begins transmitting not only the historical data contained in the buffers, but also a real time transmission of all sensor data to the central office. Control is then passed to process 1008 in which an on-going monitoring of limits is made. These may be the limits as discussed in connection with FIGS. 7A-C, or may be different set of physician programmable limits set by a physician by a transmission from the central office. These not need be the same limits. Control is then passed to decision step 1010 in which a determination is made as to whether the cease alarm condition has been reached. This process is optional as in certain embodiments it may not be appropriate to cease transmitting at all even after biometric parameters have returned to normal. The cease alarm condition could be input by a physician from the central office, or from an visiting nurse present at the remote site, or could be automatically generated through a return of the patient's biometric parameters to a prolonged period of normalcy. If a determination is made in the negative that a

cease alarm condition has not been reached then control is passed to decision step 1012.

In decision process 1012 a determination is made as to whether a confirmation sequence has been initiated by the central office. If it has then control is passed to process 1014 for implementation of the confirmation sequence. A confirmation sequence provides additional data on the patient's condition to be used in assessing the severity of the patients condition. The confirmation sequence can include a request by the central office in video or audio form to the user to indicate whether in their subjective opinion the alarm condition warrants a physician's attention. The confirmation sequence can include a question and answer sequence generated from the Q&A file downloaded from the central office. The confirmation sequence can also include a snapshot or live camera feed of the patient obtained by the portable patient monitoring device or the patient monitoring computer which is sent to the central office. Control is then passed from process 1014 back to process 1006 for a continuation of the transmission of real time data to the central office. Alternately, if in decision step 1012 a negative determination is made, i.e., that no confirmation is requested by the central office, then control is passed directly to process 1006.

If in process 1010 a determination is made that a cease alarm condition has been reached, e.g. that biometric parameters have returned to normal then control is passed to process 1016 for the imposition of a delay period during which biometric parameters continue to be transmitted to the central office. This interval is shown in

FIG. 8 between times T3-T4. When the interval has elapsed data transmission to the central office may be terminated. Control is then passed to decision 1018 in which a determination is made as to whether a reset of limit request has been sent from the central office to the remote site portable patient monitor. These new limits may be automatically generated at the central office or may be input by a doctor at the central office. They may be appropriate when the patient needs to be more closely monitored. If this determination is in the affirmative then control is passed to process 1020 in which the limit memory is reset. Control is then returned to process 1000 discussed above. Alternately if in decision step 1018 a determination is made that no physician reset of the reprogammable limits is requested, then control is directly returned to process 1000. The methods outlined above in processes 1000-1018 have the benefit of minimizing the communications between the central office and the remote site while assuring that critical detailed patient data is transmitted to the central office in a timely manner. Because the data transmitted to the central office is time stamped, a full record of the patient's biometric parameters including normal and abnormal readings can be reconstructed from the received information.

FIG. 10B shows the processing connected with the central office in an embodiment of the invention. The process begins at decision step 1054 in which a determination is made as whether an alarm event has been detected and data is being received from the remote site. If that determination is in the affirmative then control is passed to process 1056 in which all the buffer data from the remote site plus a real time feed from that site is prepared for viewing by the health care professional.

Control is then passed to process 1058 in which the medical care provider is notified by pager, monitor, telephone or any other a number of means and the data is made available to the medical care provider (MCP) in real time. The historical data from the buffer is included in the information provided to the MCP. Control is then passed to decision process 1060 in which a determination is made as whether a confirmation of the alarm condition has been programmed into the protocol for the remote site. If confirmation is appropriate control is passed to process 1064. In process 1064 a Q&A sequence, a video feed or a still image of the patient may be obtained to help confirm the patient's condition. Control is then passed to process 1066. Alternately, if in decision process 1060 a determination is made that no confirmation protocol is called for in the event of an alarm condition then control is passed directly to process 1066. In process 1066 the biometric data on the patient as well as any confirmation data, e.g. images or Q&A results are made available to the MCP. Control is then passed to decision process 1068. In decision process 1068 a determination is made as to whether the MCP desires to reset threshold conditions and/or the combination of biometric parameter value(s) required to trigger an alarm condition. If that determination is in the negative then control returns to decision step 1054 discussed above. Alternately if that determination is in the affirmative then control is passed directly to process 1070 in which the MCP is queried as to what new limits and limit combinations are required for the biometric parameters. These new limits are transmitted from the central office to the portable patient monitoring device and the limit memory is updated with the new limits.

Control is then returned to process 1054 for the processing of the next event or alarm condition received from a remote site.

FIGS. 11-17 are process flow diagrams of the processes at the remote site for monitoring specific disease states according to an embodiment of the invention. These processes can be downloaded from the central office as part of a management record or can be contained in the portable patient monitor and selected from a menu of options displayed on that monitor. Each of the following processes may be accompanied by additional processes to enhance the functionality of the patient monitoring system at the remote site. These additional processes include: authentication of patient identity, visual or still images of the patient, buffering of patient data, etc..

FIG. 11. Management of fluid balance:

Edema is an abnormal accumulation of fluid in the tissue spaces, cavities or joint capsules of the body that may cause swelling and pain in the affected area. A physician whose patient presents with a history of recurrent edema may wish to have the patient continuously monitored for early signs of fluid retention. A system for performing this monitoring is described in the process flow diagram of FIG. 11.

In process 1102 the patient is monitored by a device strapped to his or her ankle that can detect presence of, and relative change in the circumference of the ankle indicating edema. The signal from the monitoring device is then transmitted

to the portable patient monitoring device or the PMC for processing using short range half duplex RF transmission, or some other means of transmission. In process 1104, the signal from the monitoring device is compared against a specified range of values. Control is then passed to decision process 1106. In decision process 1106 a determination is made as to whether the biometric parameters in this case ankle swelling is within the specified range of values. If a determination in the negative is reached, i.e. that ankle swelling exceeds the specified range of values then control is passed to process 1108. In process 1108 a central monitoring station (e.g. a remote monitoring nurse) is automatically notified of the patient's condition. Alternately, if in decision process 1106 a determination is made that swelling is within range then control is returned to process 1104.

FIG. 12 Sleep disorders

A patient may have a history of night-time hypoxia or sleep apnea. These conditions involve low blood oxygen levels due to a variety of conditions, such as difficulty in breathing, etc. Low blood oxygen may lead to consequences such as fatigue, loss of alertness, and possibly some tissue damage. Additionally, low blood oxygen due to hypoxia or sleep apnea may be surrogate markers for some other, more serious, disease condition. Accordingly, the patient's physician may well be interested in monitoring these conditions while the patient is sleeping. A system for monitoring these conditions is described in the process flow diagram of FIG. 12.

The patient at risk for hypoxia during sleep and/or sleep apnea wears a device to monitor oximetry and/or to detect respiratory airflow and/or chest wall excursions, as shown in process 1202. The signal from the device is then transmitted to the portable patient monitoring device or the PMC for processing. If necessary, the signal may be sent to a patient monitoring computer for processing using short range half duplex RF transmission, or some other means of transmission. Control then passes to process 1204. In process 1204 the signal from the monitoring device is compared against a specified range of values for the biometric parameters being monitored. Control is then passed to decision process 1206. In decision process 1206 a determination is made as to whether the signal from the monitor is within the specified range of values. If that determination is in the affirmative control returns to process 1204 for continued monitoring of the patient. If the determination is in the negative, e.g. that values exceed the specified range(s) then control is passed to process 1208. In process 1208 the patient is then awakened. Next, in step 1210, a central monitoring station (e.g. a remote monitoring nurse) is automatically notified of the patient's condition.

FIG. 13 Arrhythmia management:

Arrhythmia is any disturbance in the electrical rhythm of the heart. An arrhythmia is an unstable series of disturbances in heartbeats, and may be associated with serious medical conditions, such as congestive heart failure or myocardial

infarction. As such, a patient prone to development of an arrhythmia may be at high risk for serious cardiovascular consequences. That patient's physician would understandably wish to monitor the patient to determine the occurrence, extent and nature of an arrhythmia using electrocardiography (ECG) each day. A system for monitoring for arrhythmias is described in the process flow diagram of FIG. 13.

In operation, the patient is prompted, once per day, to use an ECG device, as shown in process 1302. Subsequently control is passed to process 1304. In process 1304 instructions for using the device are displayed on an appropriate display panel, of the portable patient monitor or the PMC, for example. Control is then passed to process 1306. In process 1306 the signals generated by the ECG sensor are monitored. Monitoring may take place at the portable monitoring device or the PMC. If necessary, the signal may be sent to the PMC from the ECG sensor using short range half duplex RF transmission, or some other means of wireless transmission. Control is then passed to decision process 1308. In decision process 1308 a determination is made as to whether the ECG values are within a specified range of acceptable values. If the values are within an acceptable range control is passed to process 1310. In process 1310 if the signal from the monitor is within the specified range of values, then the system displays the results and also displays management techniques for the patient. Alternately, if in decision process 1308 a determination is made that the patients ECG values are outside the specified range then control is passed to process 1312. In process 1312 a central monitoring station (e.g. a remote monitoring nurse) is automatically notified in an appropriate way, and

data values are transmitted to the central monitoring station. As will be obvious to those skilled in the art ECG monitoring may also be used for detecting other conditions of the heart such as ischemia.

FIG. 14 Monitoring for exacerbations of airway disease.

Peak expiratory flow rate in a patient can be used as an indicator of serious respiratory problems. For example, decreased peak expiratory flow rate can be indicative of lung collapse, pneumonia, or pulmonary edema, as well as airway disease such as asthma. Understandably, if the patient has airway disease, or is at risk for airway disease, then the patient's physician would want to monitor the patient's peak expiratory air flow. A system for monitoring peak air flow is described in the process flow diagram of FIG. 14.

In step 1402, the patient is beckoned and prompted to use the peak expiratory flow meter, once per day. Next, in step 1404, instructions are displayed for the patient to use the spirometer or other peak flow sensor device. The peak flow test is then performed, as indicated in step 1406. The signal from the device is then transmitted to the portable patient monitoring system for processing. If necessary, the signal may be sent to a patient monitoring computer for processing using short range half duplex RF transmission, or some other wireless means of transmission. The test value is thereby recorded, as shown in step 1408. Until the test has been repeated three times, the patient will be directed to repeat the test, as indicated by

steps 1412 and 1410. After the third test such test control will be passed to process 1414. In process 1414 the system will then query the patient for a self-assessment of the patient's condition. This may be accomplished by using a display menu containing a variety of choices, as shown in step 1414, for example: "symptom-free", "mild shortness-of-breath", "moderate shortness-of-breath", etc., from which the patient selects the appropriate response. Another menu alternative is a linear scale, with "best" and "worst" marked at opposing ends, whereupon the patient selects a point along the scale corresponding to their symptom state. Alternatively, the patient may enter the self-assessment in other ways, such as entering general notes about their self-assessed condition. After the query process control is passed to decision process 1416.

In decision process 1416 the signal from the monitoring device is compared against a specified range of values. If the values are not within the acceptable range control is passed to process 1418. In process 1418 the central monitoring station (e.g. a remote monitoring nurse) is automatically notified in an appropriate way, and graphs of recent peak flows and pulmonary symptom scores are transmitted to the central monitoring station. The portable patient monitor may in addition instruct the patient to undertake certain therapeutic steps and to repeat the peak flow measurements at a specified time. Alternately, if in decision process the values are determined to lie within an acceptable range control is passed to process 1420. In process 1420 the signal from the monitoring device the system compares the signal with the highest patient value that has been previously stored. Next, the system

generates a pulmonary symptom score and a pulmonary management plan based on the NIH Asthma Guidelines (NILTPublication 97-4053, October 1997).

FIG. 15 Wound Assessment:

Patients with healing wounds need to be checked on a regular basis. This is for obvious reasons: improperly healing wounds can lead to serious infection, gangrene, and possibly even death. Especially in the context of post-operative care, wound assessments need to be performed on a periodic basis. Understandably, the patient's physician would want to monitor the patient's wound. A system for monitoring wound healing is described in the process flow diagram of FIG. 15.

In operation, the patient is prompted, at an appropriate frequency, to assess their wound through an appropriate video system, in process 1502. Such a video system is preferably a digital video system, to facilitate transmission and processing of the video images. The patient exposes their wound to the video system, and the image or images is recorded, as shown in step 1504. Next, in step 1506, the patient is prompted to assess the wound through measurements and symptoms. The measurements of the wound may be made in a variety of ways. In one embodiment, the diameter or circumference of the wound is measured with electronic calipers or a transparent template with circles arranged in "bull's eye" pattern laid over the wound. The evaluation of the wound may also be accomplished by pattern matching processes implemented on an electronic image of the wound obtained by a video or

still camera on the portable patient monitor. The patient can register symptoms through a series of self-assessment questions. In one embodiment, these questions may be "Has the size of the wound changed?", "Has the color of the wound changed?", "Is there an odor to the wound?", "Is the wound more painful?" The answers to these questions is stored in the portable patient monitor or PMC for transmission to the central office. The data may be sent to a patient monitoring computer for processing using short range half duplex RF transmission, or some other means of transmission. The data from these assessments is then recorded, as shown in step 1508. Control is then passed to decision process 1510. In decision process 1510 a determination is made as to whether the data, e.g. answers and measurements are within a specified range. If they are control is passed to process 1518. In process 1518 the data is stored in a patient file at the central monitoring facility. Alternately, if the data is not within a specified value for either the assessment results or for the image processing of the wound video, then in step 1512, appropriate information on wound management is displayed for the patient. Next, in step 1514, the recorded data is transmitted to the patient's physician or other healthcare worker, in a central monitoring facility.

FIG. 16 Monitoring for exacerbations of respiratory disorders.

Patients with a history of cardiorespiratory disease may experience difficulty in absorbing oxygen from the air and delivering it, through the blood system, to

various body tissues. These difficulties can lead to fatigue, muscle atrophy, death of the affected tissue, and other life-threatening conditions. Understandably, the patient's physician will want to monitor the state of the patient's disease. A system for monitoring the patient is described in the process flow diagram of FIG. 16.

In process 1604, the patient is prompted twice a day (or at a different frequency) to use a pulse oximeter to monitor his/her oxygen saturation (SaO_2). Next, in process 1606, instructions for using the pulse oximeter are displayed. The patient then performs the SaO_2 test, as shown in process 1608. The signal from the pulse oximeter may be transmitted to the portable patient monitor or the PMC for processing. The data may be sent to a patient monitoring computer for processing using short range half duplex RF transmission, or some other wireless means of transmission. The signal is then recorded, as shown in step 1610. Control is then passed to decision process 1612. In decision process 1612 a determination is made as to whether the SaO_2 value is within an acceptable range. If it is control is passed to process 1624. If it is not control is passed to decision process 1614. In decision process 1614 a determination is made as to whether this is the second test. If it is not control is passed to process 1616 for a repeat of the test. Subsequently control returns to process 1610. If alternately in decision process 1614 a determination is made that the test has already been repeated, then the patient will be prompted to use a different finger in process 1618 and the test will be repeated in process 1620. If the signal value in the new finger is within an acceptable range as determined in decision process 1622, then the results are stored in process 1624 for later

transmission and the patient is notified in process 1626 that the signal value results are acceptable.

If the signal value for the different finger is not within an acceptable range as determined in decision process 1622 , then control is passed to process 1630 in which the patient is directed to perform a peak expiratory flow maneuver and to capture the results using a spirometer, for example. Additionally, the patient is instructed to place a stethoscope on the patient's chest in appropriate positions to record heart sounds. Then in process 1632 the patient may be asked to provide additional information such as a self-assessment by answering questions ("Do you feel short of breath?"), or using other diagnostic instruments, or by prompting the patient to describe how the patient feels in the patient's own words. The patient is then prompted to standby for instructions from the central monitoring station. Finally, all information is recorded, in process 1634 and the recorded information, including trend charts stored from previous pulse oximetry, for example, is transmitted to the central monitoring station, as shown in process 1634.

FIG. 17 Diabetes Management: Insulin adjustment

Management of diabetes can be very complex, and yet such management is crucial to maintaining the health of a diabetic patient. The central measurement for monitoring and managing diabetes is blood glucose. Understandably, a diabetic patient's physician would want to monitor the patient's blood glucose levels, and

provide feedback to the patient regarding disease management. FIG. 17 shows a process flow diagram of a system for managing a diabetic patient's disease.

In operation, the patient is prompted to perform a glucoscan using a blood glucose monitoring device, as shown in step 1702. Instructions on how the patient should use the device are displayed on the display of the portable patient monitor or PMC in process 1704. The device is then used by the patient to perform the test, and determine the blood glucose level in process 1706. The signal from the glucose monitoring device may be transmitted to a patient monitoring computer for processing using short range half duplex RF transmission, or some other means of transmission. The signal is then recorded in process 1708. Control is then passed to decision process 1710. In decision process 1710 a determination is made as to whether the signal value is within an acceptable range. If it is not then control is passed to process 1712 in which the system informs the patient what dose of insulin to take.

If, however, the blood glucose level is abnormally high or low, then control is passed to process 1714 in which the patient is prompted to make a self-assessment. This may be accomplished by using a display menu or an audio question sequence followed by recording of responses. For example: "are you dizzy?", "are you febrile?", "are you thirsty?", etc., are questions the patients may be asked. In an alternate embodiment a menu lists alternatives in a linear scale, with "best" and "worst" marked at opposing ends, whereupon the patient selects a point along the scale corresponding to their symptom state or states. Alternatively, the

patient may enter the self-assessment in other ways, such as entering general notes about their self-assessed condition. Next, in step 1716, the patient is prompted to take vital sign measurements using devices, such as stethoscopes or blood pressure cuffs, etc., that have been either discussed above or are known to one of skill in the art. Then in process 1718 the results of these measurements are recorded and then transmitted to a central monitoring station, with graphs, for analysis by a clinician or other health care worker.

The foregoing description of embodiments of the present invention has been presented for purposes of illustration and description only. It is not intended to be exhaustive or to limit the invention to be forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in the art.

What is Claimed is:

1. A computer implemented method for managing the care of a subject with at least one condition, and the method for managing comprising the acts of:

determining a protocol for monitoring the subject, the protocol including at least one biometric parameter to be monitored and at least one response associated therewith;

monitoring the at least one biometric parameter; and

executing the at least one response associated with the biometric parameter when the biometric parameter is beyond a selected threshold.

2. The method of claim 1, wherein the selected threshold comprises at least one of: a value, range of values, and a rate of change in a value.

3. The method of claim 1, wherein the determining act further comprises the act of:

retrieving from among a plurality of disease protocol records a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored and at least one response associated therewith.

4. The method of claim 1, wherein the determining act further comprises the acts of:

retrieving from among a plurality of disease protocol records a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored and at least one response associated therewith, and the at least one response including a dosage of a medication.

5. The method of claim 1, wherein the determining act further comprises the act of:

retrieving from among a plurality of disease protocol records a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored and at least one response associated therewith, and the at least one response including training data associated with a sensor for monitoring the at least one biometric parameter.

6. The method of claim 1, wherein the determining act further comprises the act of:

retrieving from among a plurality of disease protocol records a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored and at least one response associated therewith, and the at least one response including questions for the subject.

7. The method of claim 1, wherein the determining act further comprises the act of:

retrieving from among a plurality of disease protocol records a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored, at least one time at which to monitor the biometric parameter, and at least one response associated therewith.

8. The method of claim 1, wherein the determining act further comprises the acts of:

retrieving from among a plurality of disease protocol records a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored, at least one time at which to monitor the biometric parameter and at least one response associated therewith, and the at least one response including a dosage of a medication; and

calculating an additional time at which to monitor the at least one biometric parameter to obtain information about the medication.

9. The method of claim 1, wherein the subject is located at a first site and wherein the determining act further comprises the acts of:

retrieving from among a plurality of disease protocol records at a central office a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored and at least one response associated therewith;

translating the protocol record to a management record, and the management record including computer code for monitoring the biometric parameter;

downloading the management record to a portable subject monitor at the first site; and

wherein further the monitoring and executing acts are performed by the portable subject monitor at the first site.

10. The method of claim 1, wherein the subject is located at a first site; and

wherein the determining act further comprises the acts of:

retrieving from among a plurality of disease protocol records a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored and at least one response associated therewith, and the at least one response including a dosage of a medication;

translating the protocol record to a management record, and the management record including computer code for monitoring the biometric parameter;

downloading the management record to a portable subject monitor at the first site; and

wherein further the monitoring and executing acts are performed by the portable subject monitor at the first site.

11. The method of claim 1, wherein the subject is located at a first site; and

wherein the determining act further comprises the acts of:

retrieving from among a plurality of disease protocol records a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored and at least one response associated therewith, and the at least one response including training data associated with a sensor for monitoring the at least one biometric parameter;

translating the protocol record to a management record, and the management record including computer code for monitoring the biometric parameter;

downloading the management record to a portable subject monitor at the first site; and

wherein further the monitoring and executing acts are performed by the portable subject monitor at the first site.

12. The method of claim 1, wherein the subject is located at a first site; and

wherein the determining act further comprises the acts of:

retrieving from among a plurality of disease protocol records a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored and at least one response associated therewith, and the at least one response including questions for the subject;

translating the protocol record to a management record, and the management record including computer code for monitoring the biometric parameter;

downloading the management record to a portable subject monitor at the first site; and

wherein further the monitoring and executing acts are performed by the portable subject monitor at the first site.

13. The method of claim 1, wherein the subject is located at a first site; and

wherein the determining act further comprises the acts of:

retrieving from among a plurality of disease protocol records a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored, at least one time at which to monitor the biometric parameter, and at least one response associated therewith;

translating the protocol record to a management record, and the management record including computer code for monitoring the biometric parameter;

downloading the management record to a portable subject monitor at the first site; and

wherein further the monitoring and executing acts are performed by the portable subject monitor at the first site.

14. The method of claim 1, wherein the subject is located at a first site, and wherein the executing act further comprises the acts of:

detecting at the first site that the biometric parameter is beyond a selected threshold;

sending from the first site to a second site, data on the biometric paremeter accumulated during the monitoring act.

15. The method of claim 14, further comprising the acts of:

receiving at the second site the data;

retrieving from among a plurality of disease protocol records at the second site a protocol record for the at least one condition, and the protocol record containing a display protocol for displaying the data; and

displaying the data in accordance with the protocol.

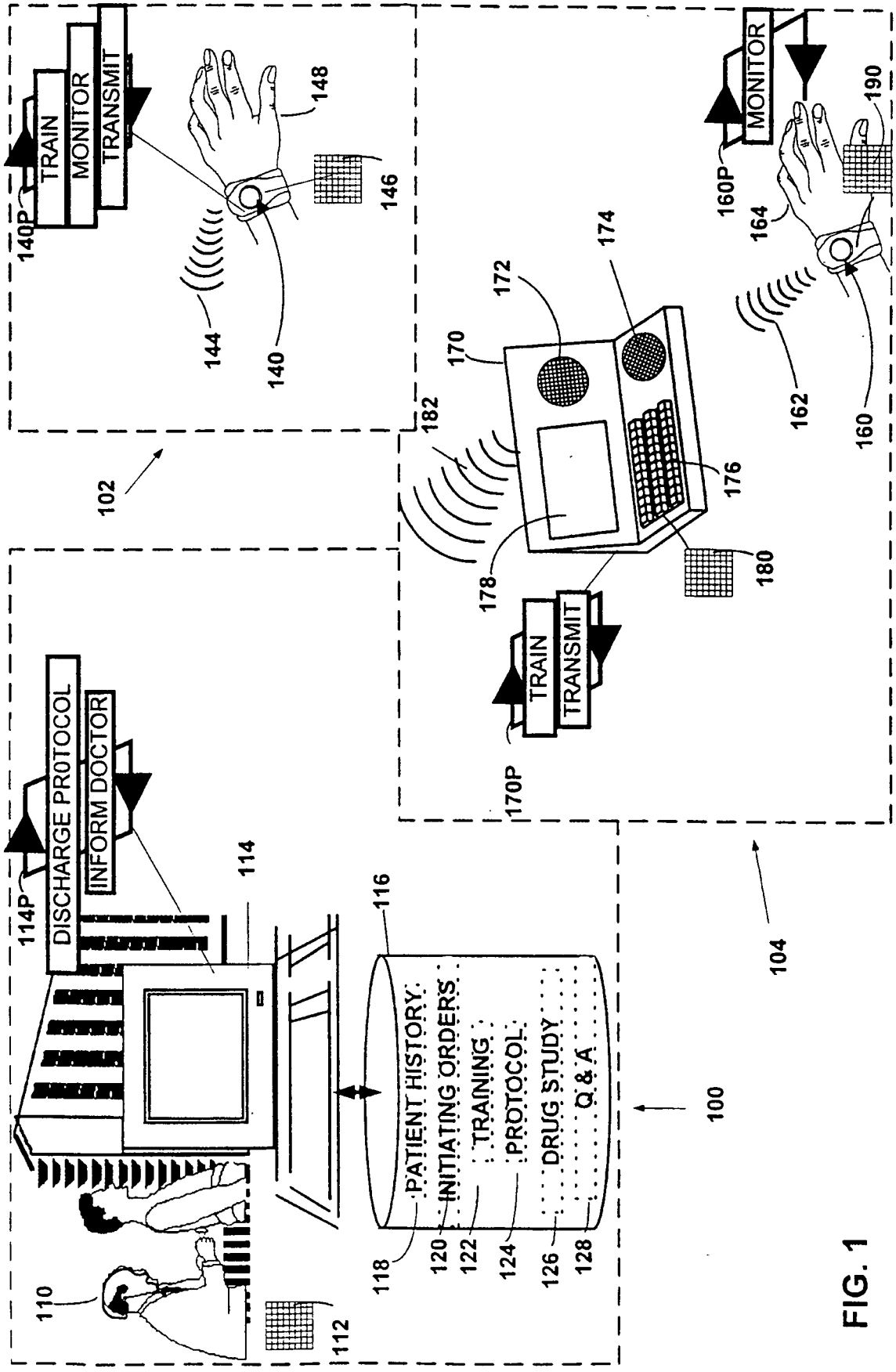

TRAIN
MONITOR
TRANSMIT
140P
148
146
144
140
102
MONITOR
160P
190
164
162
160
174
172
170
182
176
178
180
TRAIN
TRANSMIT
170P
104
DISCHARGE PROTOCOL
INFORM DOCTOR
114P
114
116
PATIENT HISTORY
INITIATING ORDERS
TRAINING
PROTOCOL
DRUG STUDY
Q & A
118
120
122
124
126
128
110
112
100

FIG. 1

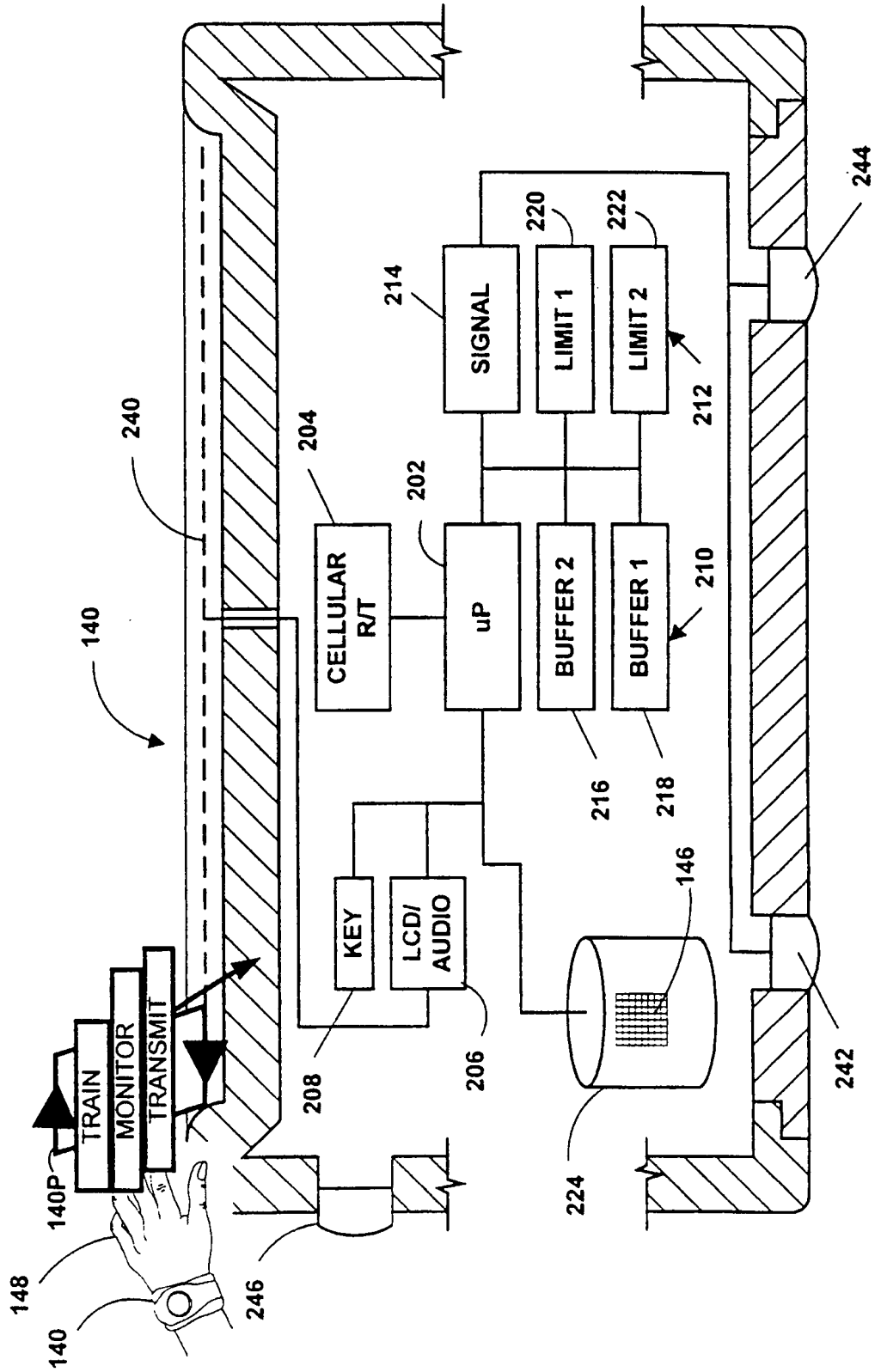

140
240
204
202
214
220
222
244
SIGNAL
LIMIT 1
LIMIT 2
212
CELLULAR R/T
uP
BUFFER 2
BUFFER 1
210
216
218
146
KEY
LCD/ AUDIO
208
206
224
242
TRAIN
MONITOR
TRANSMIT
140P
148
140
246

FIG. 2

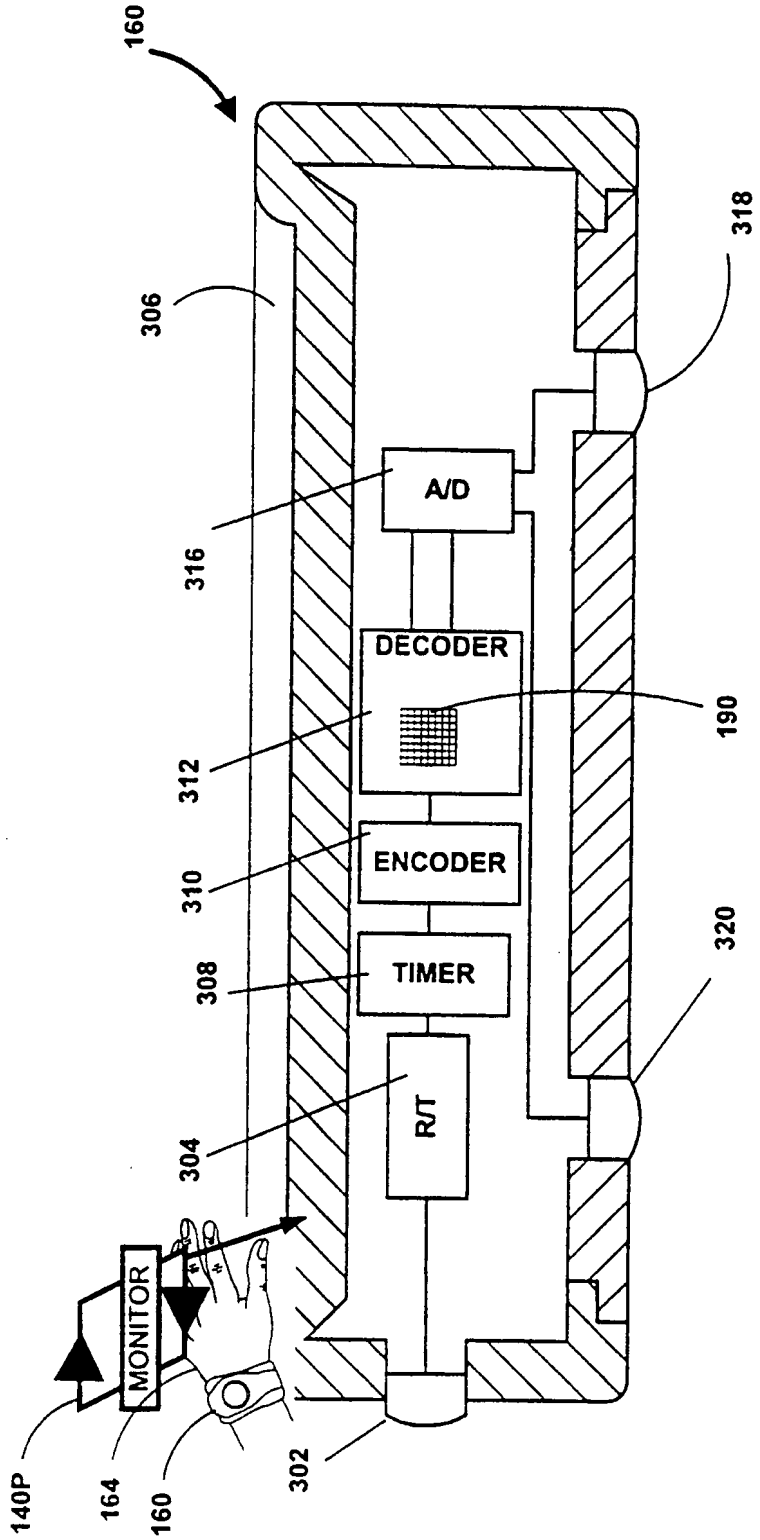

160
318
306
A/D
316
DECODER
190
312
ENCODER
310
TIMER
308
320
R/T
304
MONITOR
140P
164
160
302

FIG. 3

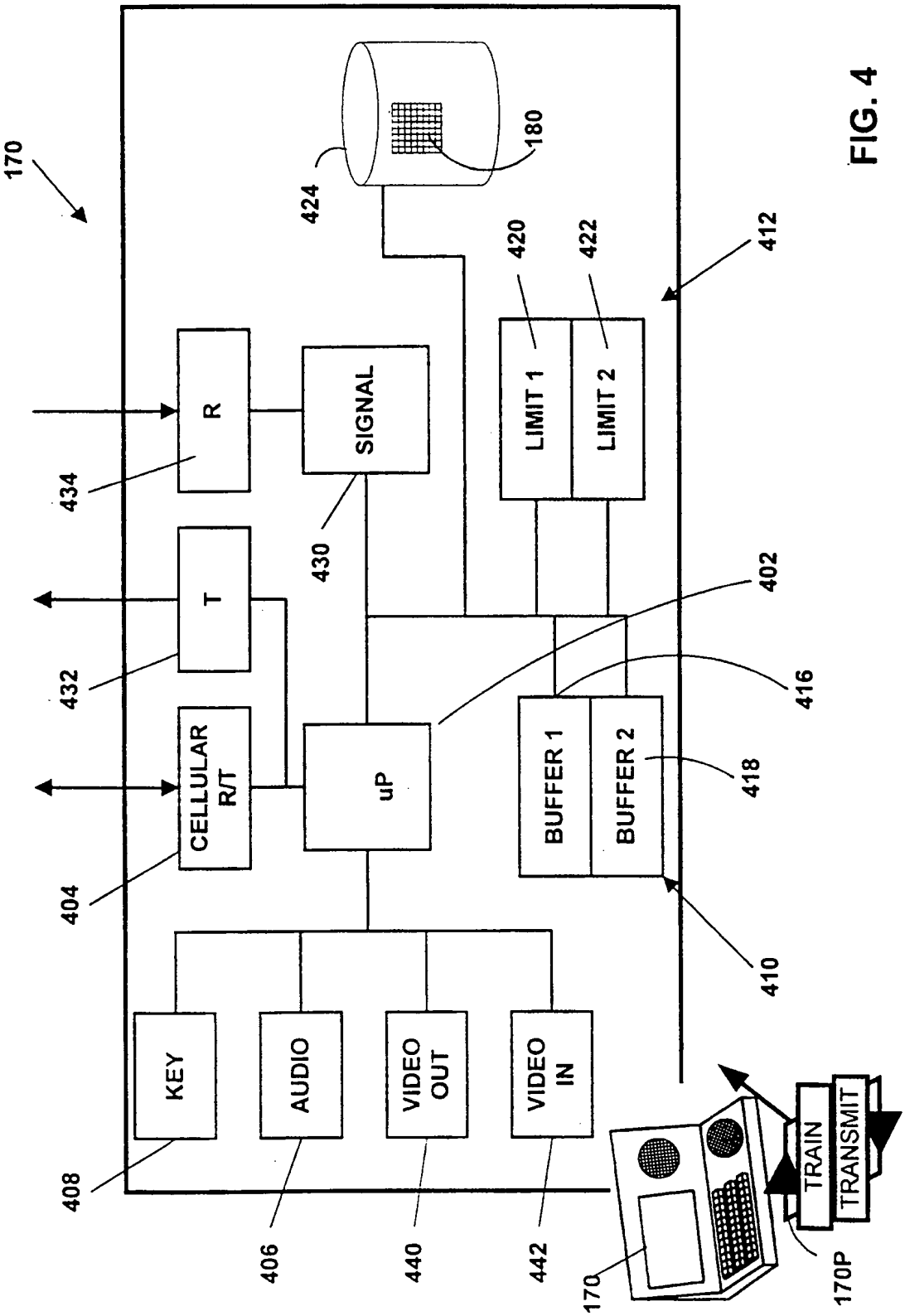

170
424
180
420
422
412
LIMIT 1
LIMIT 2
R
SIGNAL
434
430
T
432
402
416
CELLULAR R/T
uP
BUFFER 1
BUFFER 2
418
404
410
KEY
AUDIO
VIDEO OUT
VIDEO IN
408
406
440
442
TRAIN
TRANSMIT
170
170P

FIG. 4

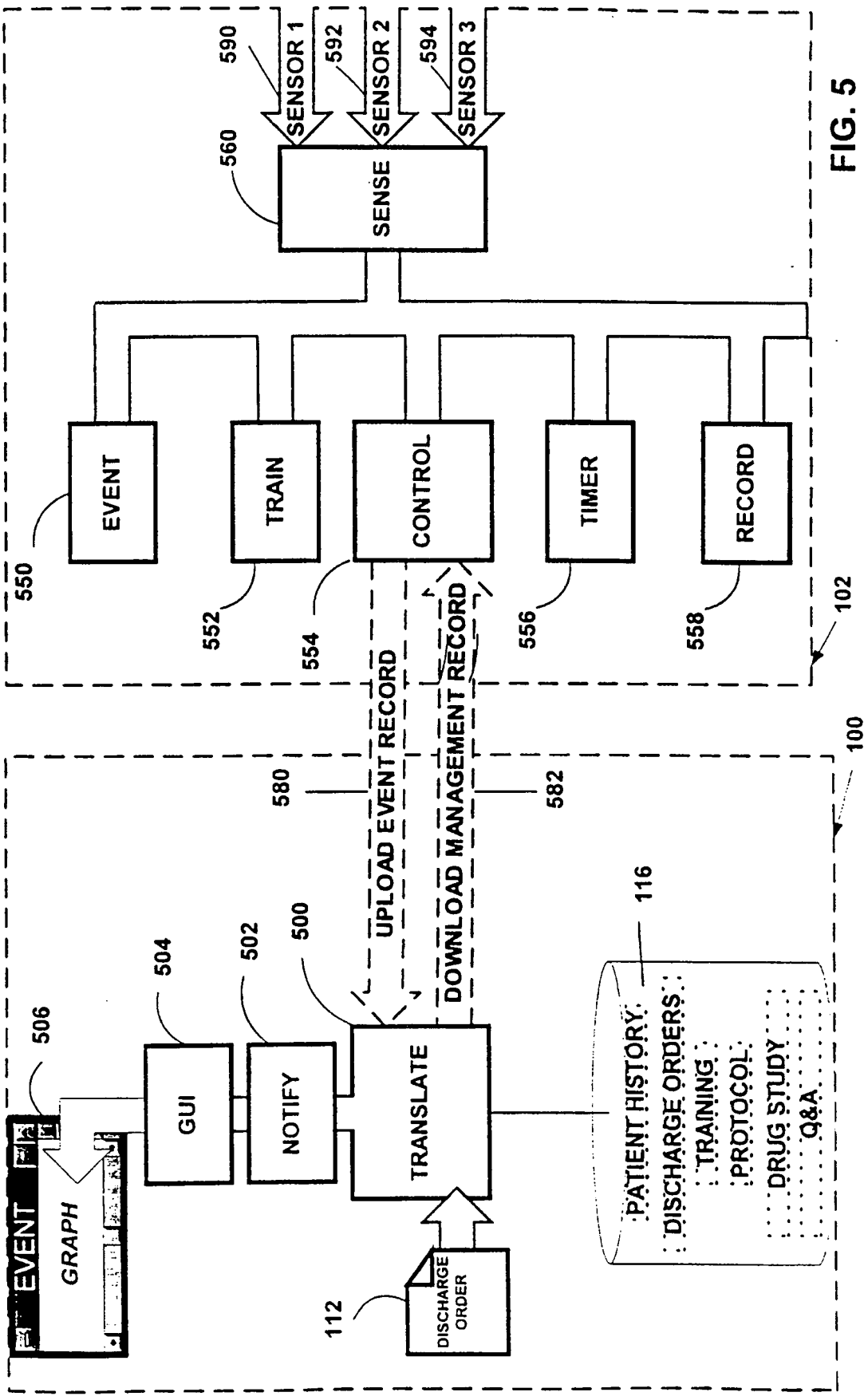

590
SENSOR 1
592
SENSOR 2
594
SENSOR 3
560
SENSE
EVENT
TRAIN
CONTROL
TIMER
RECORD
550
552
554
556
558
102
UPLOAD EVENT RECORD
DOWNLOAD MANAGEMENT RECORD
580
582
100
116
PATIENT HISTORY
DISCHARGE ORDERS
TRAINING
PROTOCOL
DRUG STUDY
Q&A
500
502
504
506
TRANSLATE
NOTIFY
GUI
EVENT
GRAPH
112
DISCHARGE ORDER

FIG. 5

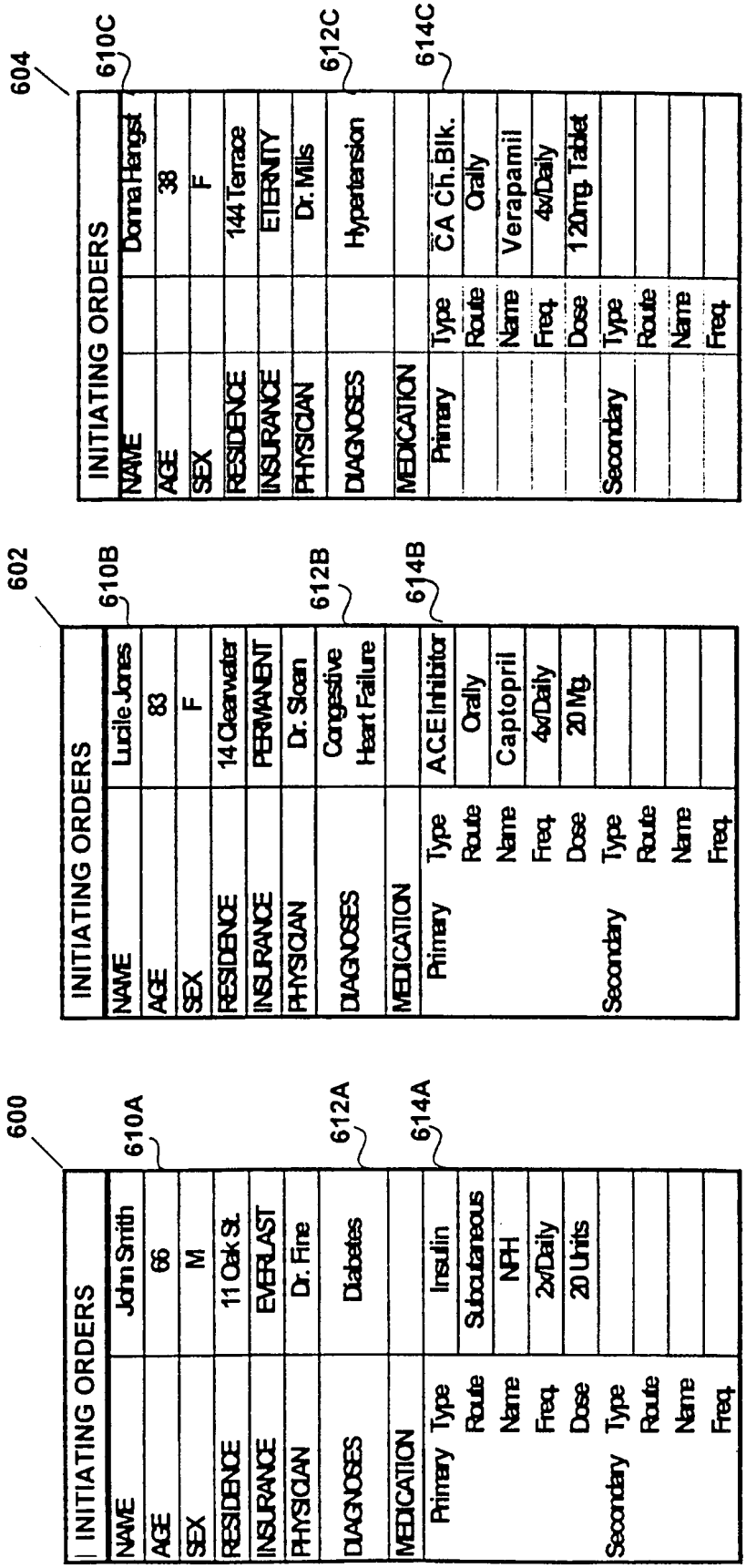
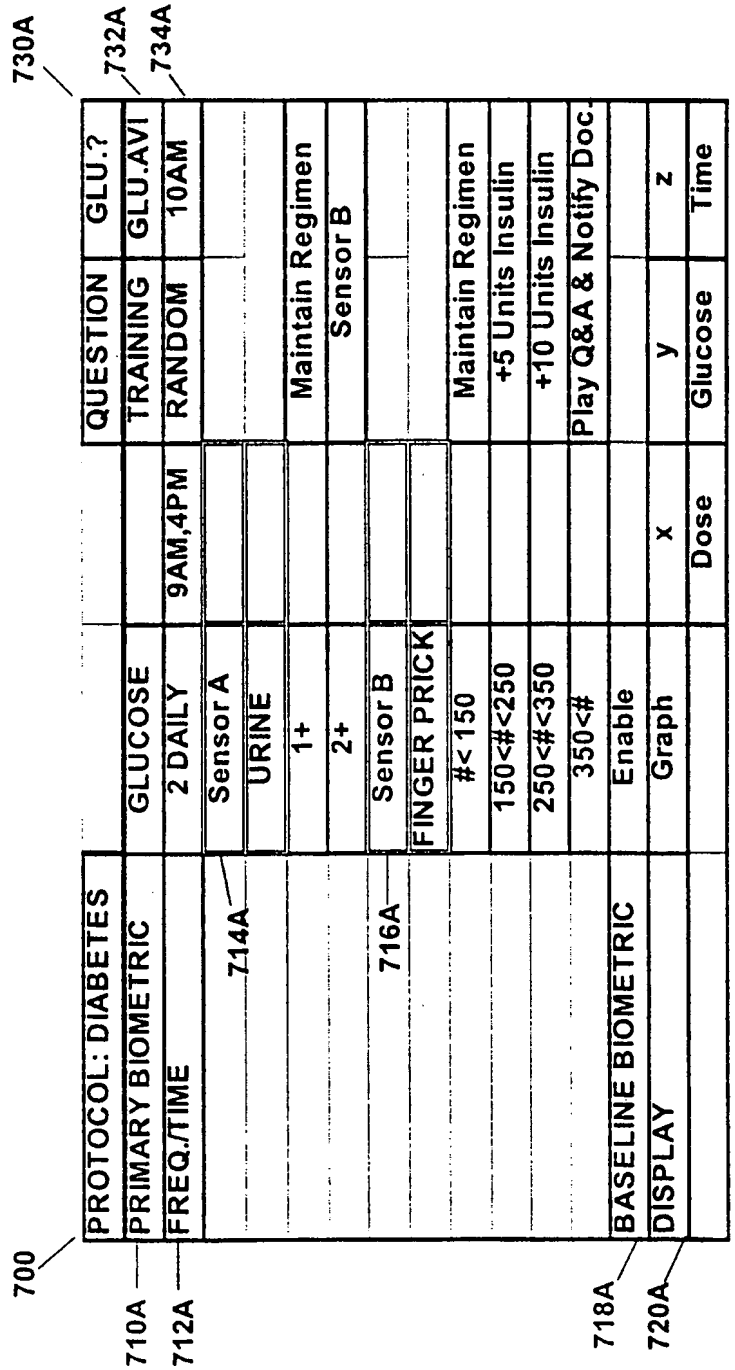


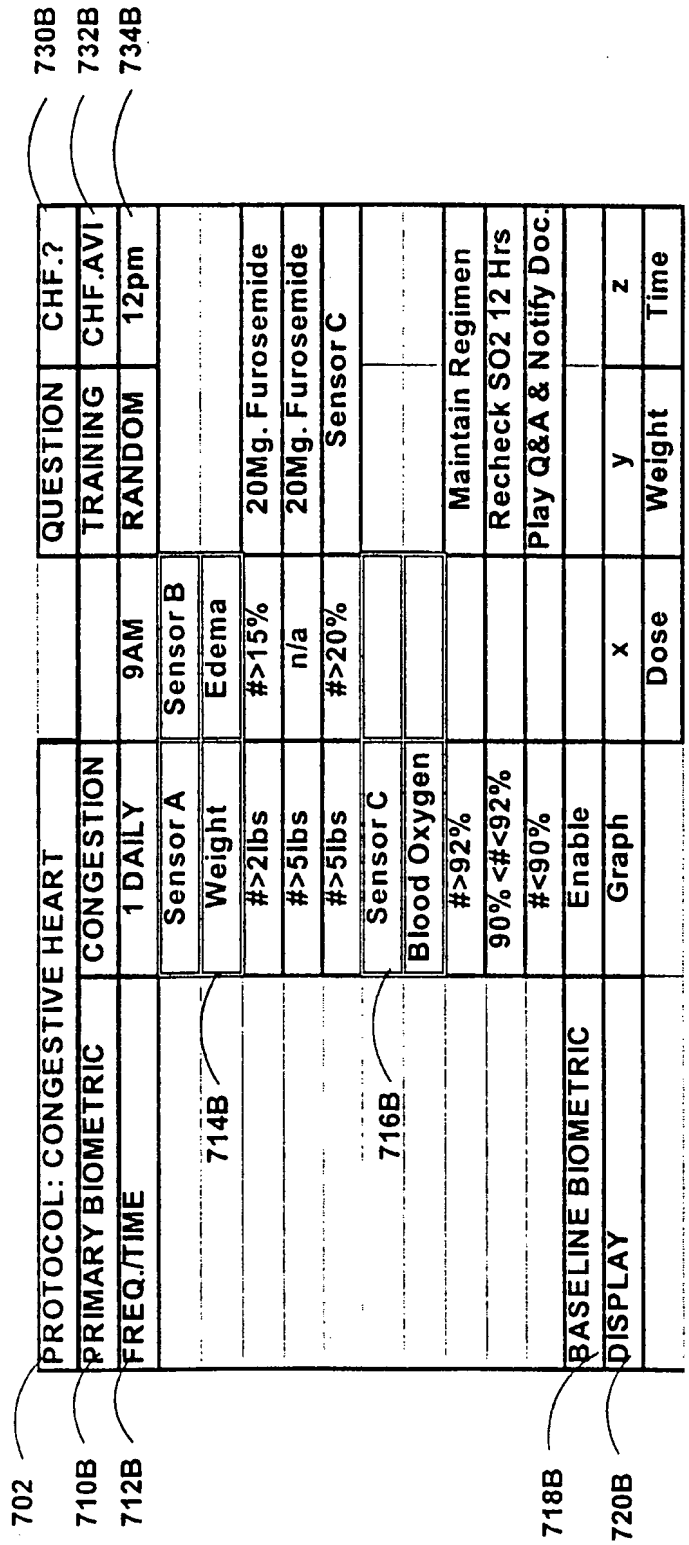
FIG. 6

INTIATING ORDERS



DIABETES
DISEASE PROTOCOL RECORD

FIG. 7A



CONGESTIVE HEART
DISEASE PROTOCOL RECORD

FIG. 7B

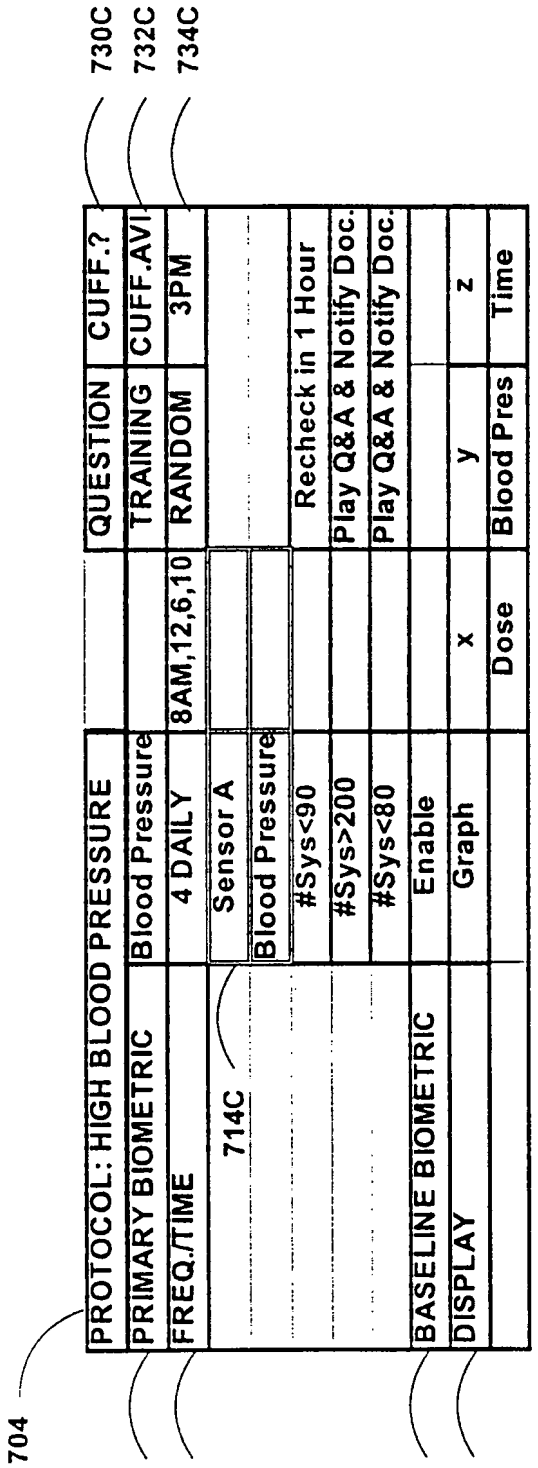


FIG. 7C

HIGH BLOOD PRESSURE
DISEASE PROTOCOL RECORD

FIG. 8B

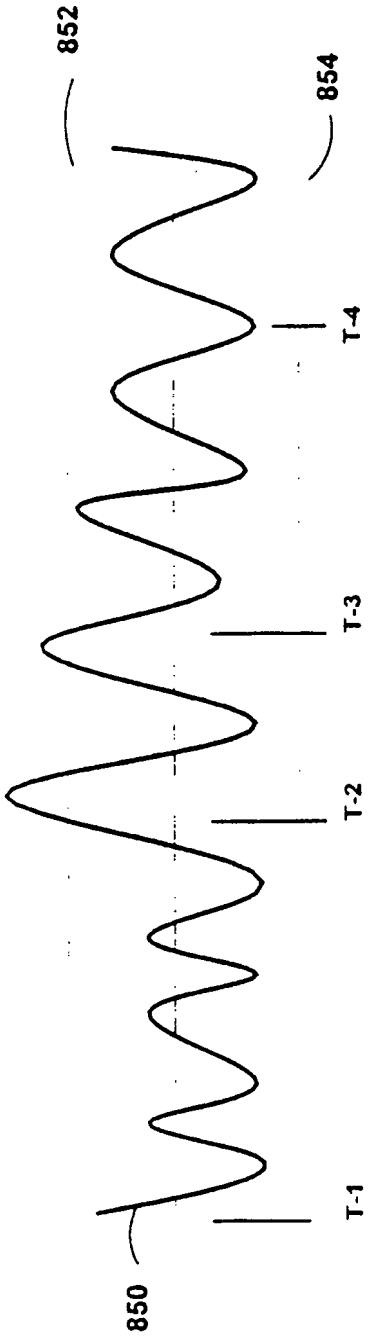
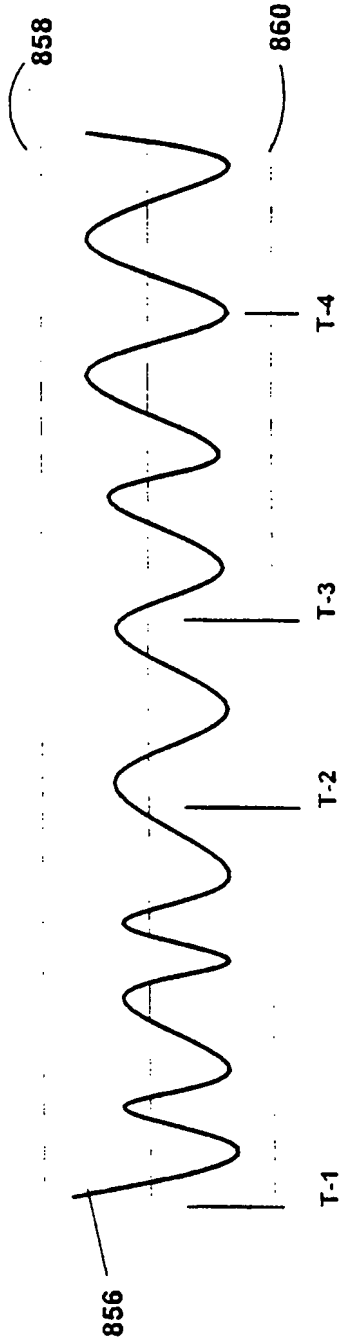


FIG. 8A



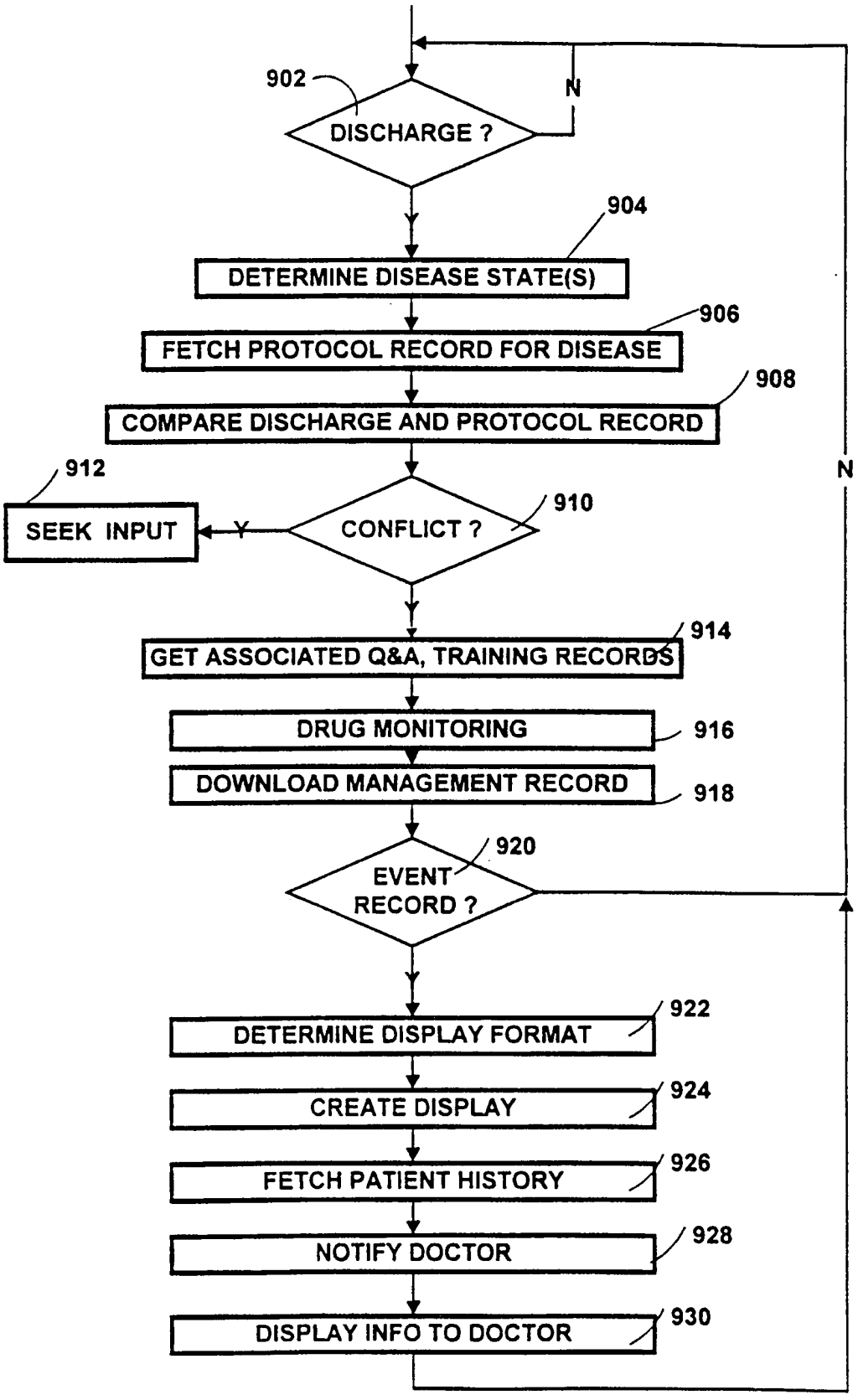

902
DISCHARGE ?
N
904
DETERMINE DISEASE STATE(S)
906
FETCH PROTOCOL RECORD FOR DISEASE
908
COMPARE DISCHARGE AND PROTOCOL RECORD
912
SEEK INPUT
Y
CONFLICT ?
910
N
914
GET ASSOCIATED Q&A, TRAINING RECORDS
DRUG MONITORING
916
DOWNLOAD MANAGEMENT RECORD
918
920
EVENT RECORD ?
922
DETERMINE DISPLAY FORMAT
924
CREATE DISPLAY
926
FETCH PATIENT HISTORY
928
NOTIFY DOCTOR
930
DISPLAY INFO TO DOCTOR

FIG. 9

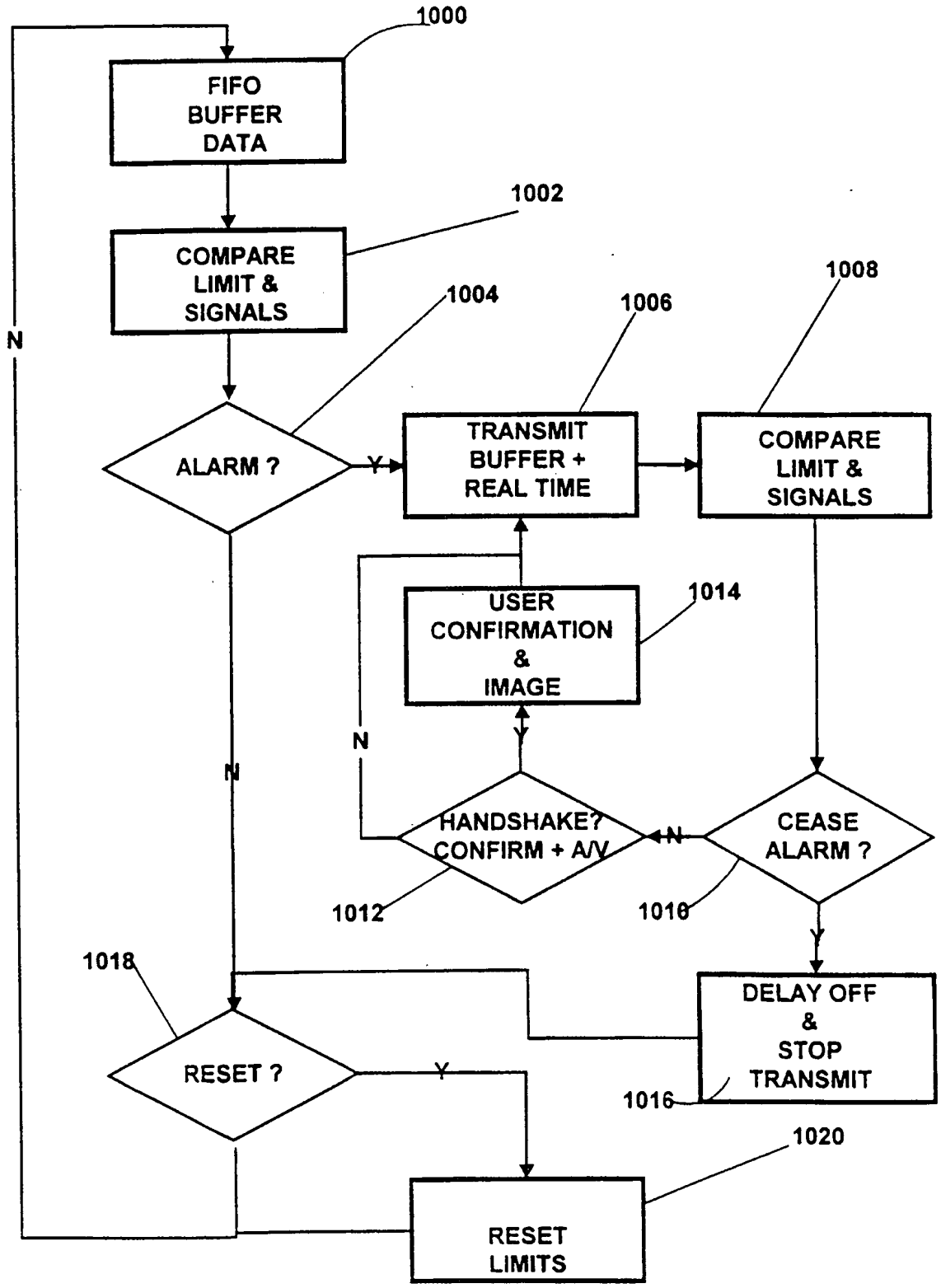

1000
FIFO BUFFER DATA
1002
COMPARE LIMIT & SIGNALS
1004
1006
1008
ALARM ?
Y
TRANSMIT BUFFER + REAL TIME
COMPARE LIMIT & SIGNALS
N
USER CONFIRMATION & IMAGE
1014
Y
N
N
HANDSHAKE? CONFIRM + A/V
N
CEASE ALARM ?
1012
1010
Y
1018
DELAY OFF & STOP TRANSMIT
RESET ?
Y
1016
1020
RESET LIMITS

FIG. 10A

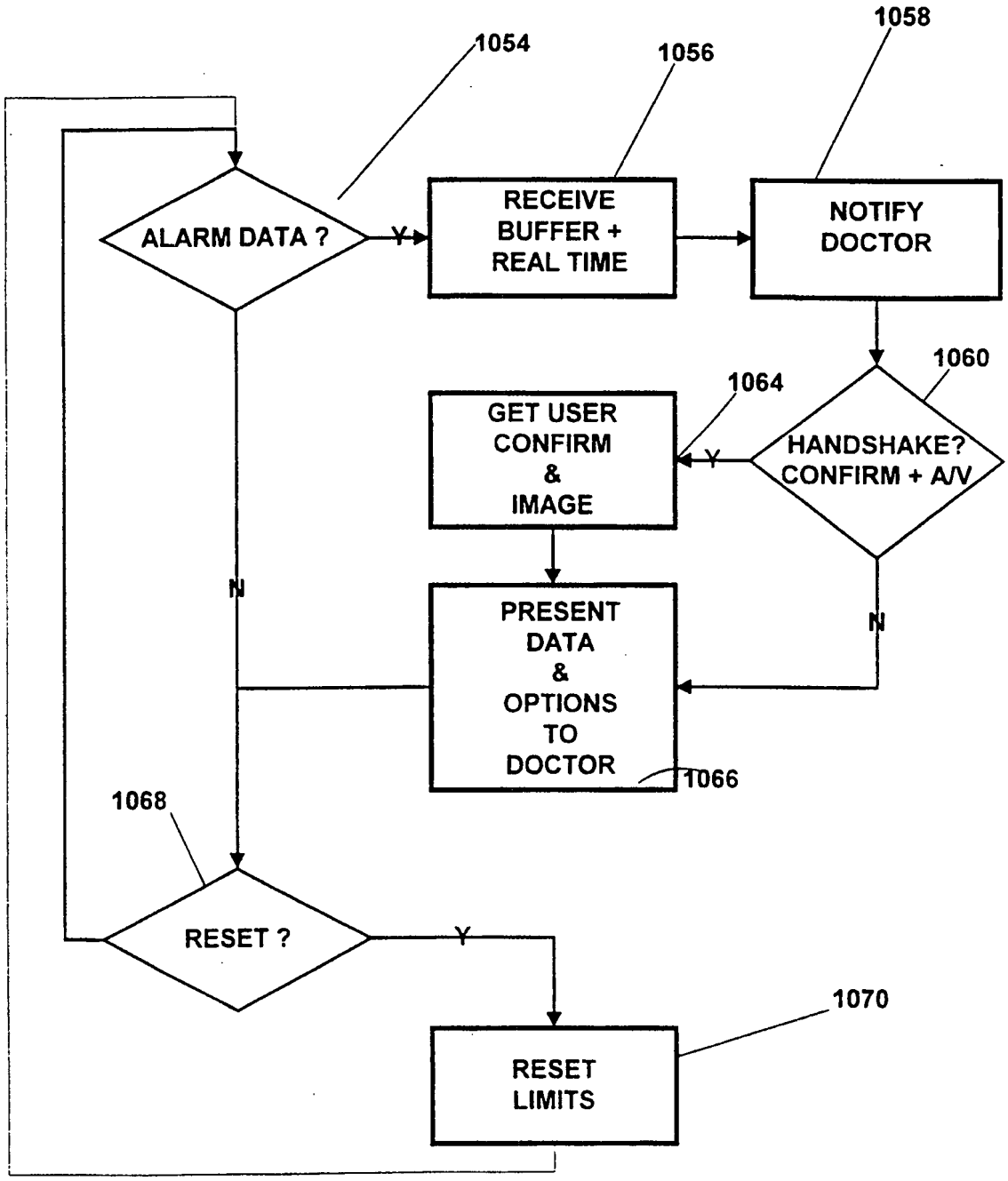

1054
1056
1058
ALARM DATA ?
Y
RECEIVE BUFFER + REAL TIME
NOTIFY DOCTOR
1060
1064
GET USER CONFIRM & IMAGE
Y
HANDSHAKE? CONFIRM + A/V
N
N
PRESENT DATA & OPTIONS TO DOCTOR
1066
1068
RESET ?
Y
1070
RESET LIMITS

FIG. 10B

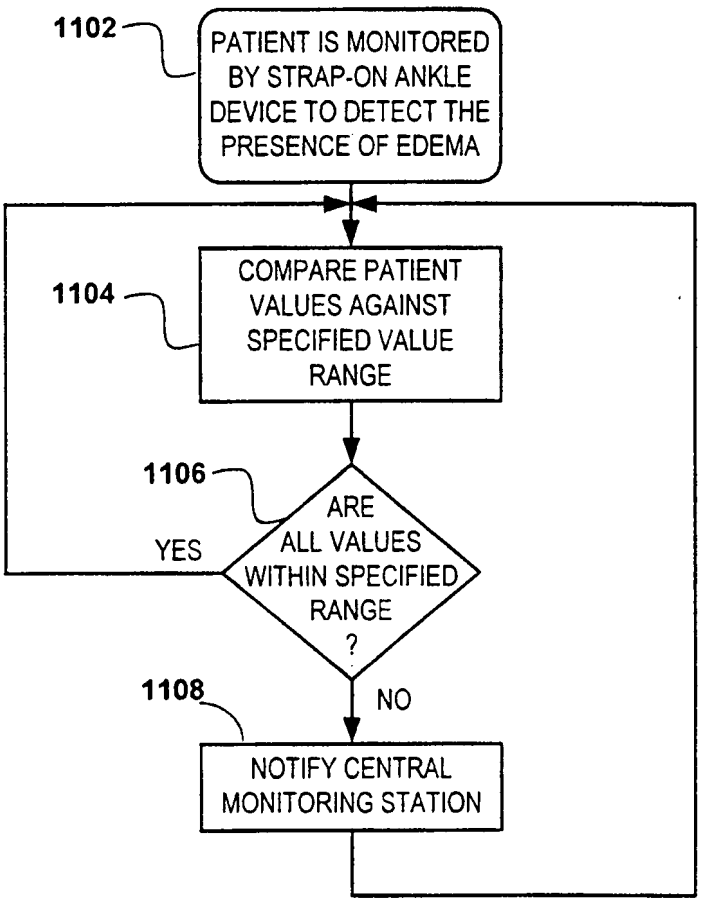

1102
PATIENT IS MONITORED BY STRAP-ON ANKLE DEVICE TO DETECT THE PRESENCE OF EDEMA
1104
COMPARE PATIENT VALUES AGAINST SPECIFIED VALUE RANGE
1106
ARE ALL VALUES WITHIN SPECIFIED RANGE ?
YES
NO
1108
NOTIFY CENTRAL MONITORING STATION

FIG. 11

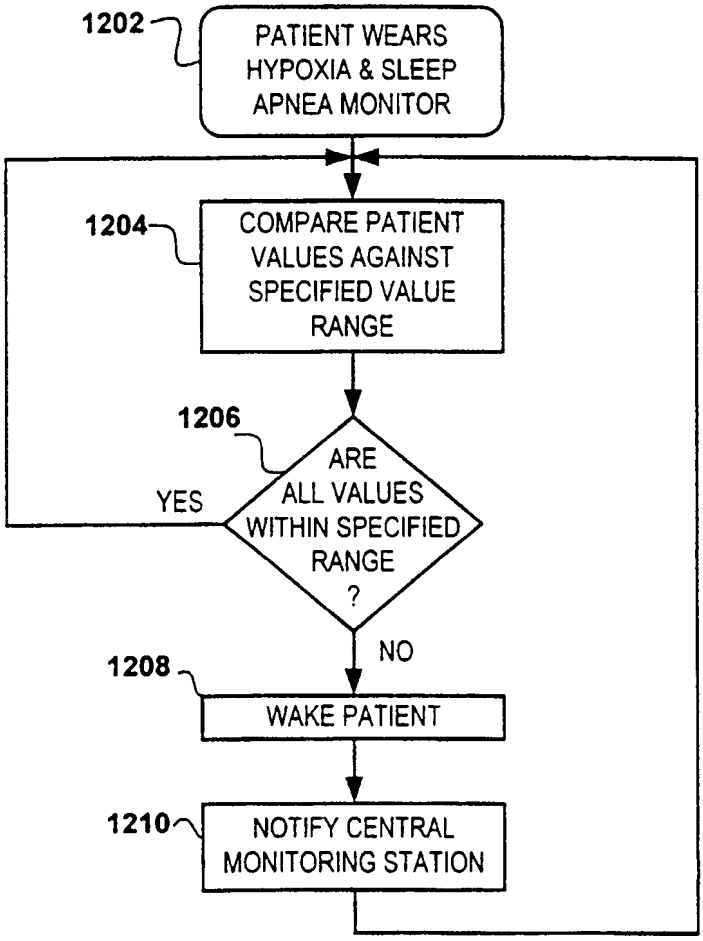

1202
PATIENT WEARS HYPOXIA & SLEEP APNEA MONITOR
1204
COMPARE PATIENT VALUES AGAINST SPECIFIED VALUE RANGE
1206
ARE ALL VALUES WITHIN SPECIFIED RANGE ?
YES
NO
1208
WAKE PATIENT
1210
NOTIFY CENTRAL MONITORING STATION

FIG. 12

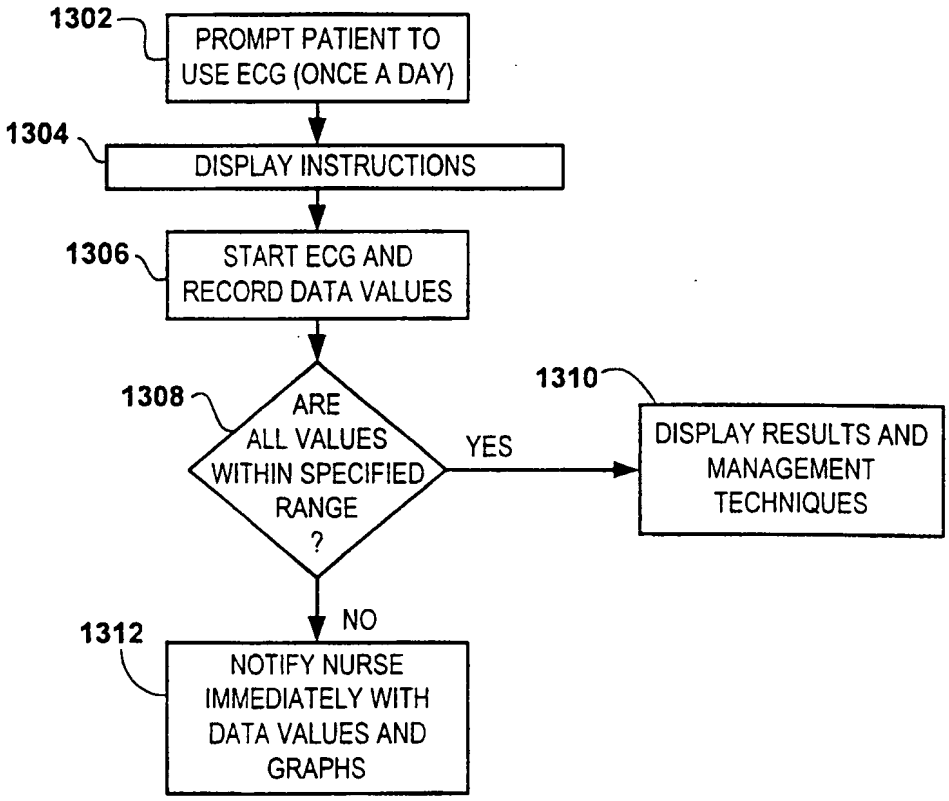

1302
PROMPT PATIENT TO USE ECG (ONCE A DAY)
1304
DISPLAY INSTRUCTIONS
1306
START ECG AND RECORD DATA VALUES
1308
ARE ALL VALUES WITHIN SPECIFIED RANGE ?
YES
1310
DISPLAY RESULTS AND MANAGEMENT TECHNIQUES
NO
1312
NOTIFY NURSE IMMEDIATELY WITH DATA VALUES AND GRAPHS

FIG. 13

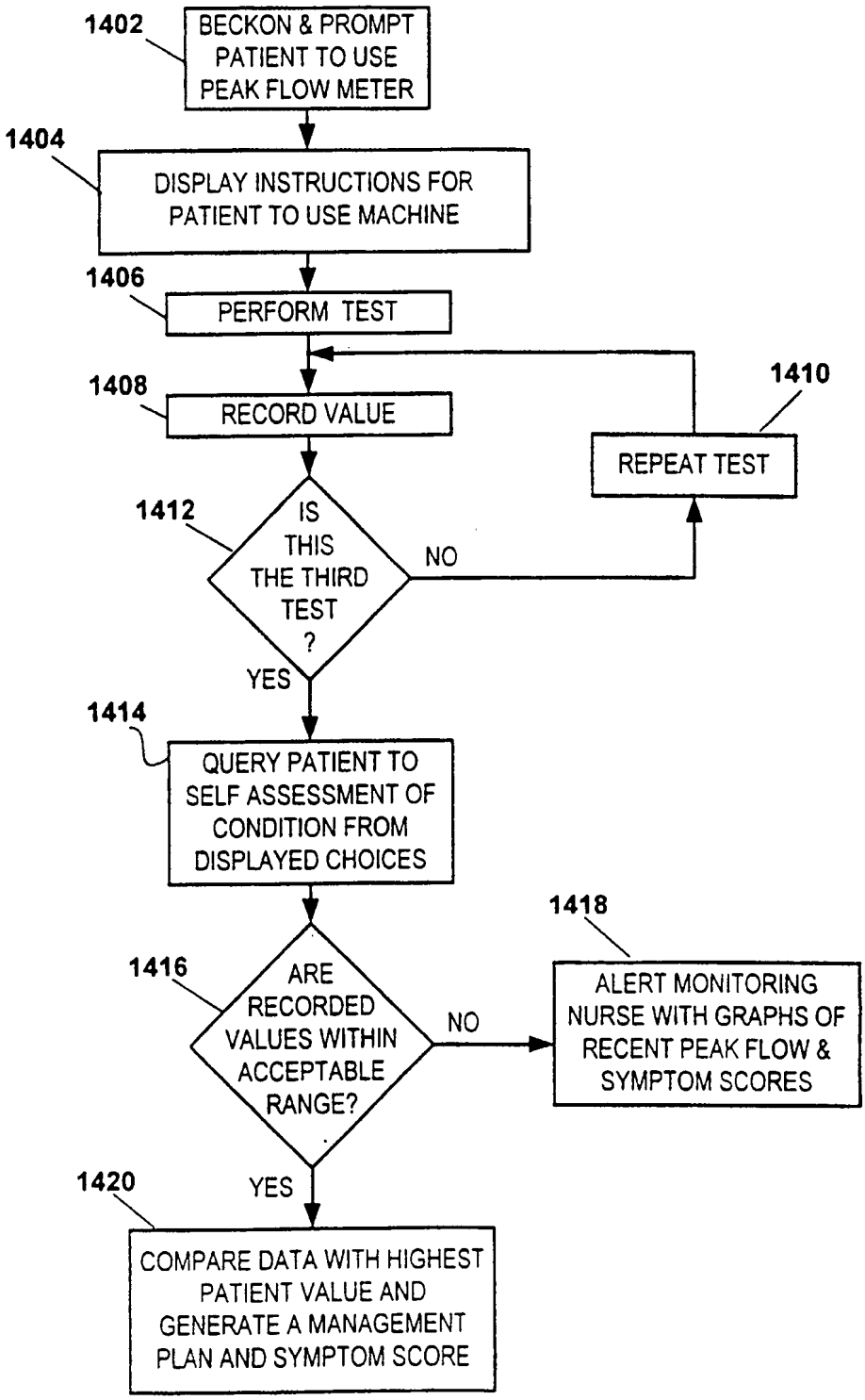

1402
BECKON & PROMPT PATIENT TO USE PEAK FLOW METER
1404
DISPLAY INSTRUCTIONS FOR PATIENT TO USE MACHINE
1406
PERFORM TEST
1408
RECORD VALUE
1410
REPEAT TEST
1412
IS THIS THE THIRD TEST ?
NO
YES
1414
QUERY PATIENT TO SELF ASSESSMENT OF CONDITION FROM DISPLAYED CHOICES
1418
1416
ARE RECORDED VALUES WITHIN ACCEPTABLE RANGE?
NO
ALERT MONITORING NURSE WITH GRAPHS OF RECENT PEAK FLOW & SYMPTOM SCORES
1420
YES
COMPARE DATA WITH HIGHEST PATIENT VALUE AND GENERATE A MANAGEMENT PLAN AND SYMPTOM SCORE

FIG. 14

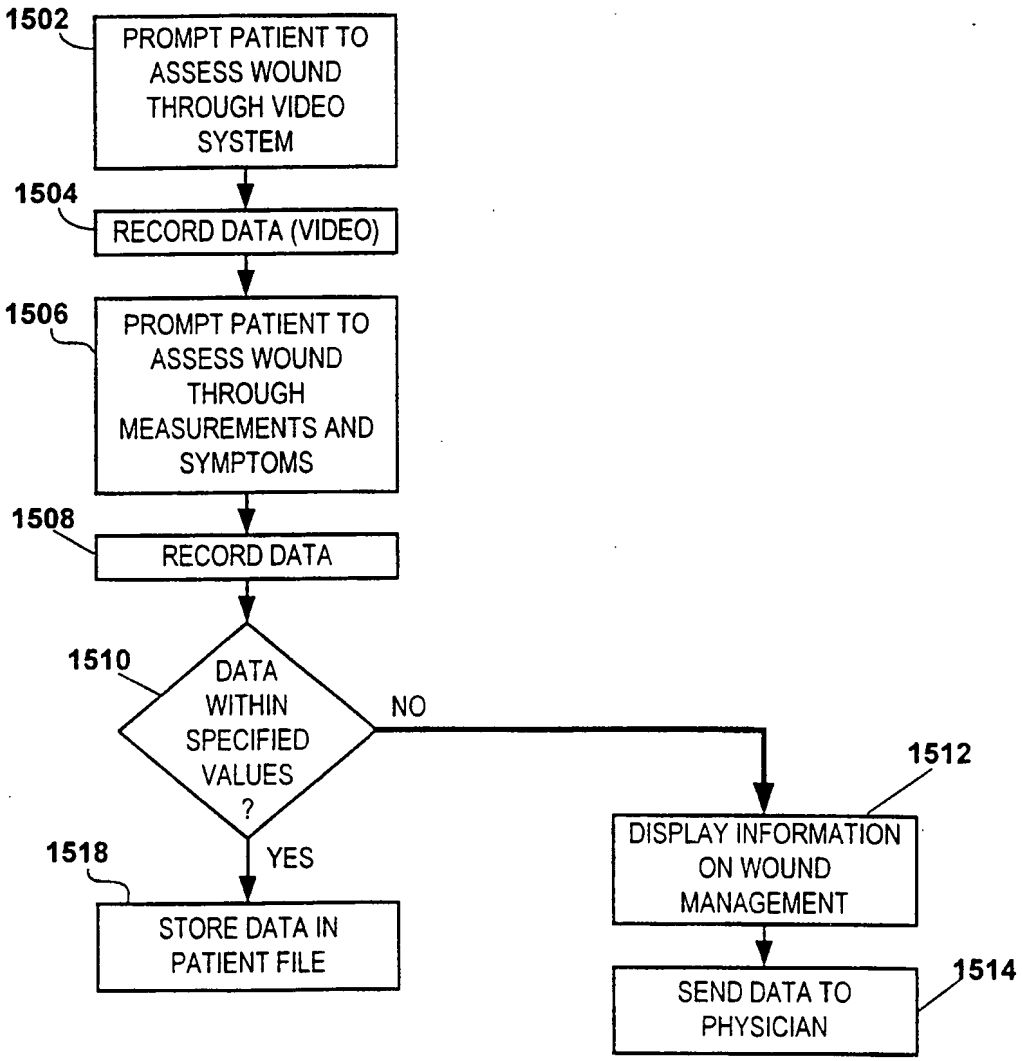

1502
PROMPT PATIENT TO ASSESS WOUND THROUGH VIDEO SYSTEM
1504
RECORD DATA (VIDEO)
1506
PROMPT PATIENT TO ASSESS WOUND THROUGH MEASUREMENTS AND SYMPTOMS
1508
RECORD DATA
1510
DATA WITHIN SPECIFIED VALUES ?
NO
YES
1512
DISPLAY INFORMATION ON WOUND MANAGEMENT
1514
SEND DATA TO PHYSICIAN
1518
STORE DATA IN PATIENT FILE

FIG. 15

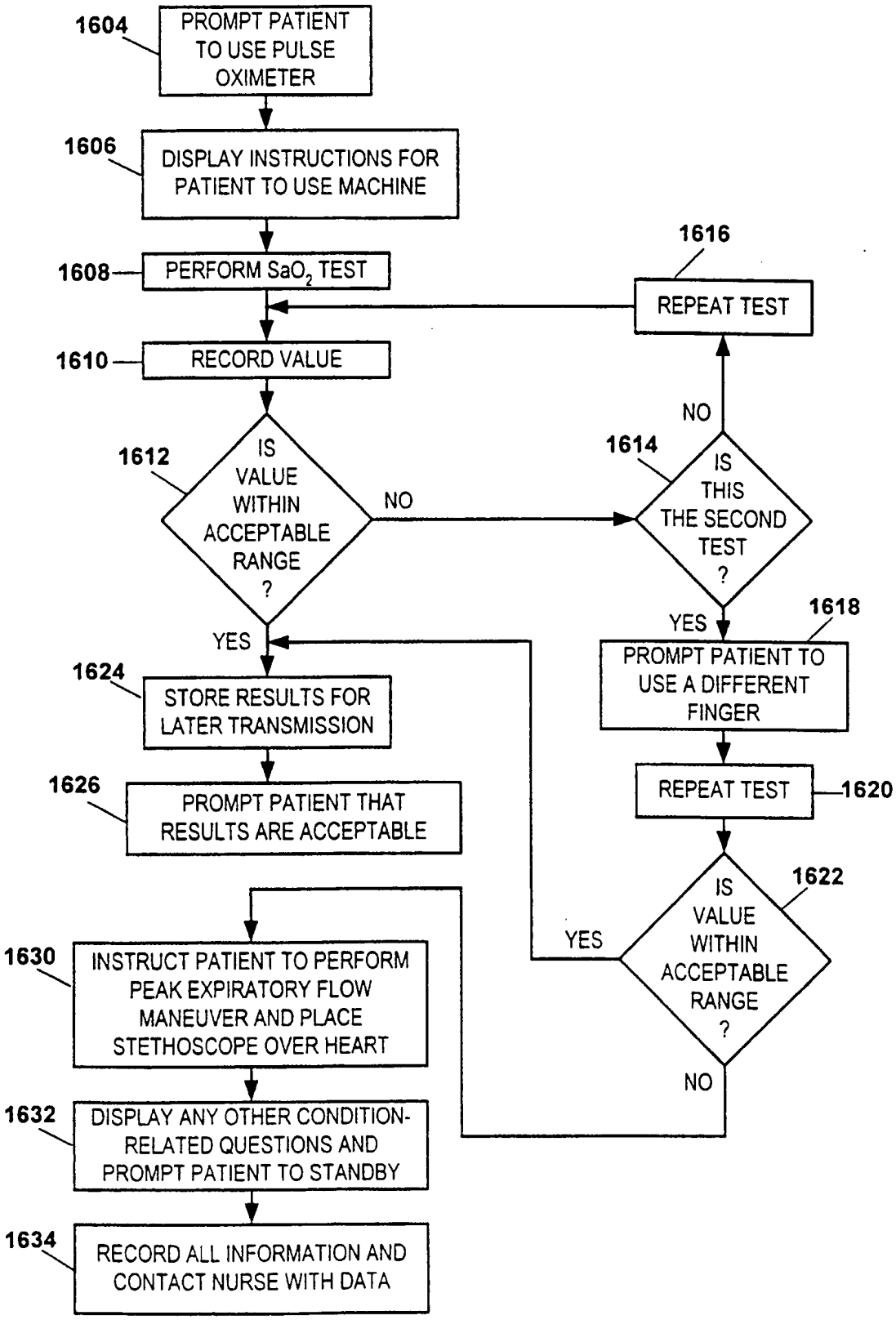

1604
PROMPT PATIENT TO USE PULSE OXIMETER
1606
DISPLAY INSTRUCTIONS FOR PATIENT TO USE MACHINE
1608
PERFORM SaO_2 TEST
1610
RECORD VALUE
1612
IS VALUE WITHIN ACCEPTABLE RANGE ?
NO
YES
1614
IS THIS THE SECOND TEST ?
NO
YES
1616
REPEAT TEST
1618
PROMPT PATIENT TO USE A DIFFERENT FINGER
1620
REPEAT TEST
1622
IS VALUE WITHIN ACCEPTABLE RANGE ?
YES
NO
1624
STORE RESULTS FOR LATER TRANSMISSION
1626
PROMPT PATIENT THAT RESULTS ARE ACCEPTABLE
1630
INSTRUCT PATIENT TO PERFORM PEAK EXPIRATORY FLOW MANEUVER AND PLACE STETHOSCOPE OVER HEART
1632
DISPLAY ANY OTHER CONDITION-RELATED QUESTIONS AND PROMPT PATIENT TO STANDBY
1634
RECORD ALL INFORMATION AND CONTACT NURSE WITH DATA

FIG. 16

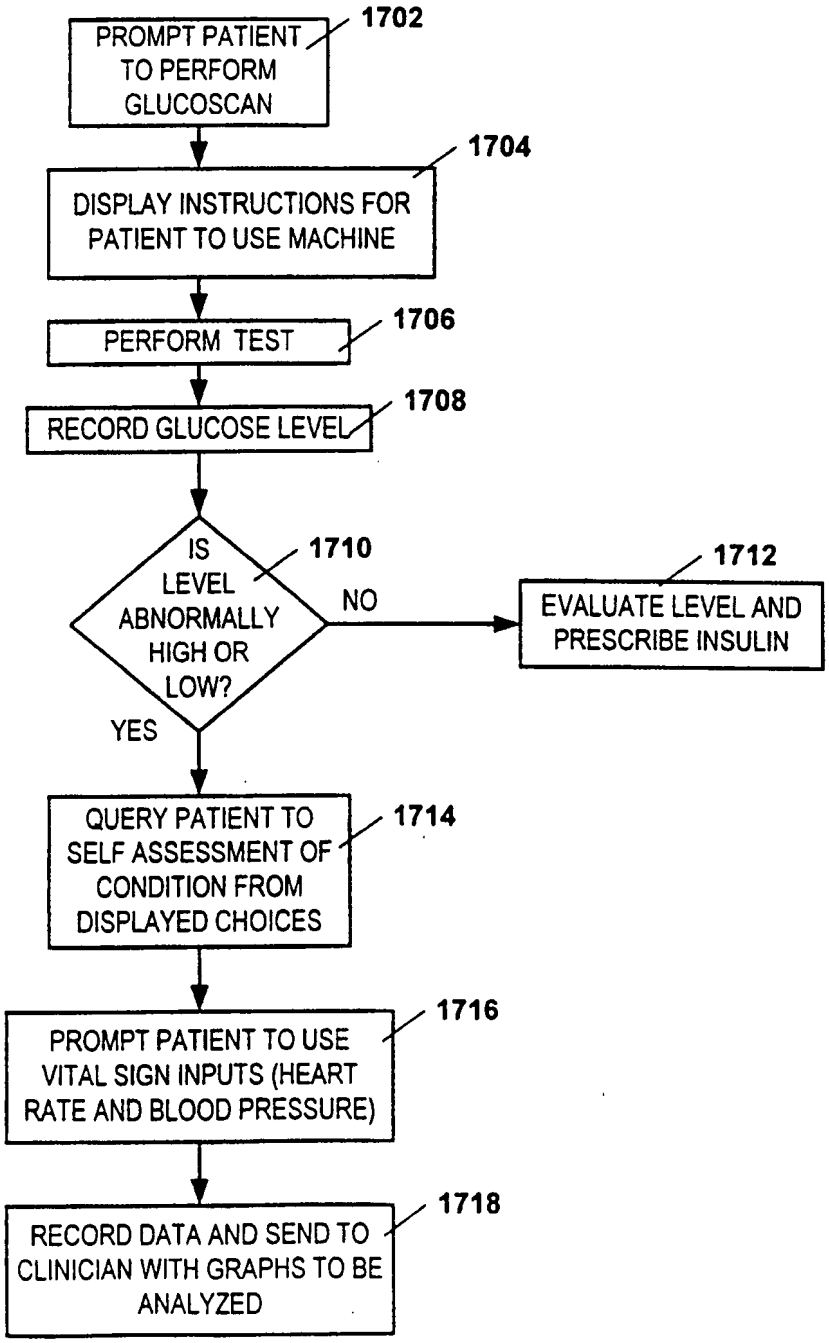

PROMPT PATIENT TO PERFORM GLUCOSCAN
1702
DISPLAY INSTRUCTIONS FOR PATIENT TO USE MACHINE
1704
PERFORM TEST
1706
RECORD GLUCOSE LEVEL
1708
IS LEVEL ABNORMALLY HIGH OR LOW?
1710
NO
EVALUATE LEVEL AND PRESCRIBE INSULIN
1712
YES
QUERY PATIENT TO SELF ASSESSMENT OF CONDITION FROM DISPLAYED CHOICES
1714
PROMPT PATIENT TO USE VITAL SIGN INPUTS (HEART RATE AND BLOOD PRESSURE)
1716
RECORD DATA AND SEND TO CLINICIAN WITH GRAPHS TO BE ANALYZED
1718

FIG. 17

INTERNATIONAL SEARCH REPORT

Int. tional Application No
PCT/US 98/08911

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G06F19/00

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 251 520 A (BUDDY SYSTEMS INC) 7 January 1988	1-4, 6-10, 12-15
Y	see page 2, line 29 - page 12, line 13; figures 1-15	5,11

Y	EP 0 342 859 A (HEALTH TECH SERVICES CORP) 23 November 1989	5,11
A	see abstract	1-4, 6-10, 12-15
	see page 2, line 43 - page 3, line 43	

A	WO 94 10634 A (ERGOMETRX CORP) 11 May 1994 see page 8, line 1 - page 9, line 37	1,3

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
3 September 1998	11/09/1998

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Int. .tional Application No
PCT/US 98/08911

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication,where appropriate. of the relevant passages	Relevant to claim No.
A	WO 96 08910 A (COHEN KOPEL H) 21 March 1996 see page 5, line 28 - page 13, line 2	1-15
A	WO 95 32480 A (SANDERS MATTHEW H ;ENACT PRODUCTS INC (US); TACKLIND CHRISTOPHER A) 30 November 1995 see page 8, line 21 - page 19, line 2; figures 1-10	1-15

1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte .tional Application No
PCT/US 98/08911

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 0787400 A	06-08-1997
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		CA 2190283 A	30-11-1995
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		JP 10500598 T	20-01-1998
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		US 5549117 A	27-08-1996
		US 5732709 A	31-03-1998

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60/081,369	10 April 1998 (10.04.98)	US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications

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Filed on	2 May 1997 (02.05.97)
US	60/081,369 (CIP)
Filed on	10 April 1998 (10.04.98)

(71) Applicant *(for all designated States except US)*: CYBER-HEALTH, INC. [US/US]; 1614 Valmont Street, New Orleans, LA 70115 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: WALKER, Cedric, F. [US/US]; 2619 Nashville Avenue, New Orleans, LA 70115 (US). KARP, Edward, W. [US/US]; 1614 Valmont Street, New Orleans, LA 70155 (US). FINE, Jonathan, M. [US/US]; 10 Bittersweet Road, Weston, CT 06856 (US).

(74) Agent: CARY, Charles, C.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

With international search report.

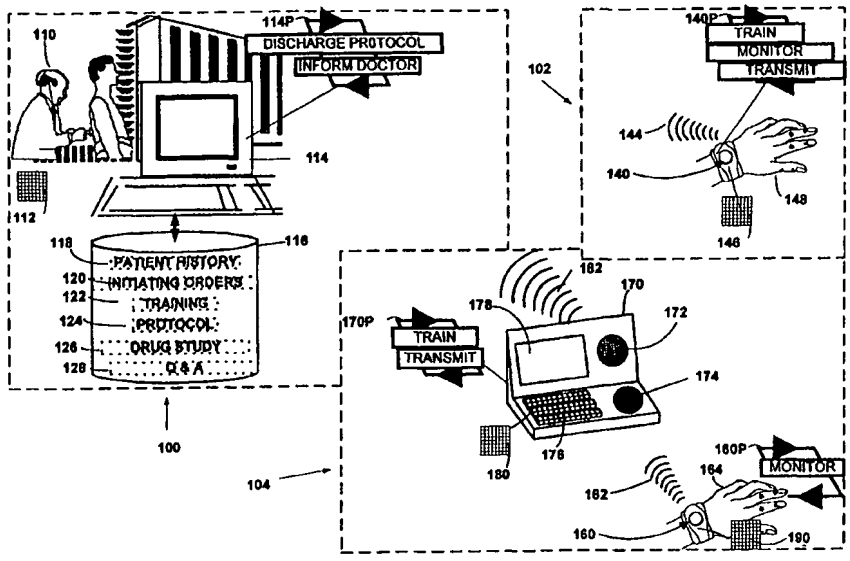
With amended claims.

Date of publication of the amended claims:
30 December 1998 (30.12.98)

(54) Title: CYBER MEDICINE DISEASE MANAGEMENT

(57) Abstract

The subject health monitoring system is designed to supplement in an embodiment of the invention the health care efforts in caring for patients confined to their homes. The system may also be utilized within a facility such as a nursing home for monitoring patients within the home. The system integrates components distributed between a hospital and/or a central monitoring office to provide improved monitoring of these patients. The system provides for the translation of initiating orders into a computerized format. The system further provides for the programming of a patient monitoring unit at the remote site with the specific protocols consistent with the diagnoses of the doctor, as indicated on the initiating order. The system further provides for computerized training and prompting of the patient to assure their compliance with the initiating orders. Additionally, the system provides for intelligent communication between the remote site and the central office when appropriate. The system provides for the transmission of relevant data from the remote site to the central office when a critical event occurs. The system also provides for notification and graphical presentment to the doctor of trending of the patients biometric parameters. The trending parameters computed and presented to the doctor are disease specific, thus making for a more timely response. Finally, the system provides for the accumulation of a statistically normalized database correlating various medications as to their efficacy, duration, and side effects.



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AMENDED CLAIMS

[received by the International Bureau on 4 November 1998 (04.11.98);
new claims 16-25 added; remaining claims unchanged (5 pages)]

16. A patient monitoring device for managing the care of a subject at a first site, and the patient monitoring device comprising:

a receiver for receiving a management record from a second site, and the management record containing at least one biometric parameter of the subject to be monitored and at least one response associated therewith;

a sensor to generate a signal corresponding to the at least one biometric parameter of the subject; and

a recorder to record the signal; and

a first logic for executing the at least one response associated with the biometric parameter when the biometric parameter is beyond a selected threshold.

17. The patient monitoring device of claim 16, further comprising:

a transmitter for transmitting an event record to the second site and the event record including the recorded signal for the at least one biometric parameter; and

wherein the at least one response includes the transmission of the event record to the second site.

18. The patient monitoring device of claim 16, further comprising:

a communication means for communicating a recommended dosage of medication to the subject; and

wherein the at least one response includes the communication to the subject of the recommended dosage.

19. The patient monitoring device of claim 16, further comprising:

a communication means for cummunicating training data associated with the recommended installation of the sensor; and

wherein the at least one response includes the communication to the subject of the training data.

20. The patient monitoring device of claim 16, further comprising:

a communication means for cummunicating to the subject questions relating to the health of the subject; and

wherein the recorder further comprises the capability of recording answers of the subject to the questions; and

wherein the at least one response includes questions for the subject.

21. The patient monitoring device of claim 16, wherein the managment record from the second site further comprises at least one time at which to monitor the biometric parameter; and

wherein the recorder records the signal at the at least one time.

22. The patient monitoring device of claim 16, further comprising:

a camera for obtaining at least one image of the subject; and

wherein the at least one response includes obtaining an image of the subject.

23. A central control for monitoring a subject with a specific condition at a first site and the central control comprising:

a plurality of disease protocol records including a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored, at least one response associated therewith;

means for retrieving the protocol record for the at least one condition from the plurality of disease protocol records;

a transmitter for transmitting the protocol record to the first site.

24. The central control of claim 23, further comprising:

a receiver for receiving an event record from the first site and the event record including a recorded signal for the at least one biometric parameter; and

means for notifying a doctor of the receipt of the event record and for displaying to a doctor the at least one biometric parameter.

25. A system for monitoring a subject with a specific condition at a first site from a second site, and the system for monitoring comprising:

a central control at the second site comprising:

a) a plurality of disease protocol records including a protocol record for the at least one condition, and the protocol record containing at least one biometric parameter to be monitored, at least one response associated therewith;

b) means for retrieving the protocol record for the at least one condition from the plurality of disease protocol records; and

c) a transmitter for transmitting the protocol record to the first site;

d) a receiver for receiving an event record from the first site and the event record including a recorded signal for the at least one biometric parameter; and

e) means for notifying a doctor of the receipt of the event record and for displaying to a doctor the at least one biometric parameter; and

a subject monitoring device for managing the care of a subject at the first site, and the patient monitoring device comprising:

a) a receiver for receiving the protocol record;

b) a sensor to generate a signal corresponding to the at least one biometric parameter of the subject;

c) a recorder to record the signal; and

d) a first logic for executing the at least one response associated with the biometric parameter when the biometric parameter is beyond a selected threshold.

e) a transmitter for transmitting an event record to the second site and the event record including the recorded signal for the at least one biometric parameter; and

wherein the at least one response includes the transmission of the event record to the second site.